A STUDY ON BIPOLAR AFFECTIVE DISORDER SUBJECTS UNDER REMISSION – QUALITY OF SLEEP AND QUALITY OF LIFE

DISSERTATION SUBMITTED

For Partial Fulfillment of the Rules and Regulations

DOCTOR OF MEDICINE

BRANCH - XVIII (PSYCHIATRY)

INSTITUTE OF MENTAL HEALTH

MADRAS MEDICAL COLLEGE,

THE TAMIL NADU DR. M. G. R. MEDICAL UNIVERSITY, CHENNAI, INDIA

APRIL 2016

CERTIFICATE

This is to certify that the dissertation titled, **"A STUDY ON BIPOLAR AFFECTIVE DISORDER SUBJECTS UNDER REMISSION – QUALITY OF SLEEP AND QUALITY OF LIFE"** is the bonafide work of **Dr. RAVIKUMAR. R,** in part fulfilment of the requirements for the M.D. Branch – XVIII (Psychiatry) examination of the Tamil Nadu Dr.M.G.R. Medical University, to be held in April 2016.

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CERTIFICATE OF GUIDE

This is to certify that the dissertation titled, **"A STUDY ON BIPOLAR AFFECTIVE DISORDER SUBJECTS UNDER REMISSION – QUALITY OF SLEEP AND QUALITY OF LIFE"** is the original work of **Dr. RAVIKUMAR. R,** done under my guidance submitted in partial fulfilment of the requirements for M.D. Branch – XVIII [Psychiatry] examination of the Tamilnadu Dr. M.G.R. Medical University, to be held in April 2016.

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DECLARATION

I, **Dr. RAVIKUMAR.R,** solemnly declare that the dissertation titled, **"A STUDY ON BIPOLAR AFFECTIVE DISORDER SUBJECTS UNDER REMISSION – QUALITY OF SLEEP AND QUALITY OF LIFE"** is a bonafide work done by me at the Madras Medical College, Chennai, under the guidance and supervision of **Dr. JEYAPRAKASH.R. MD, DPM,** Professor of Psychiatry, Madras Medical College. The dissertation is submitted to the Tamilnadu Dr. M.G.R. Medical University towards part fulfilment for M.D. Branch XVIII (Psychiatry) examination.

Place:

Date: **Dr. RAVIKUMAR. R.**

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INSTITUTIONAL ETHICS COMMITTEE
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CERTIFICATE OF APPROVAL

To
Dr.R.Ravikumar
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Madras Medical College
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Dear Dr.R.Ravikumar,

The Institutional Ethics Committee has considered your request and approved your study titled **"A study on Bipolar Affective Disorder subjects under remission – quality of sleep and quality of life" No.22052015.**

The following members of Ethics Committee were present in the meeting held on 12.05.2015 conducted at Madras Medical College, Chennai-3.

1. Prof.C.Rajendran, M.D.,	: Chairperson
2. Prof.R.Vimala, M.D., Dean, MMC, Ch-3	: Deputy Chairperson
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8. Thiru S.Rameshkumar, B.Com., MBA	: Lay Person
9. Thiru S.Govindasamy, B.A., B.L.,	: Lawyer
10. Tmt.Arnold Saulina, M.A., MSW.,	: Social Scientist

We approve the proposal to be conducted in its presented form.

The Institutional Ethics Committee expects to be informed about the progress of the study and SAE occurring in the course of the study, any changes in the protocol and patients information/informed consent and asks to be provided a copy of the final report.

16/5/15

Member Secretary, Ethics Committee

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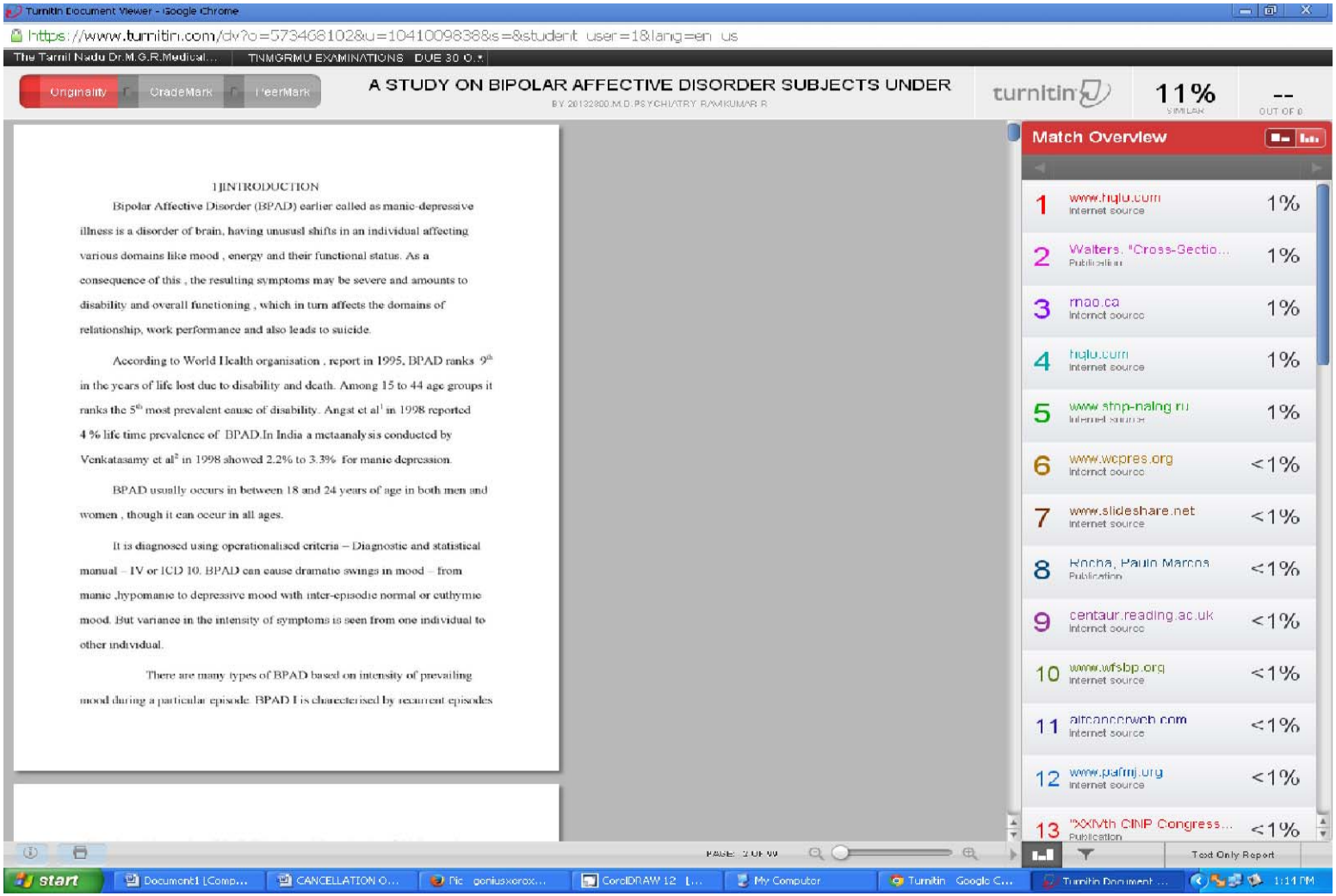
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1]INTRODUCTION
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According to World Health organisation , report in 1995, BPAD ranks 9th in the years of life lost due to disability and death. Among 15 to 44 age groups it ranks the 5th most prevalent cause of disability. Angst et al[1] in 1998 reported 4 % life time prevalence of BPAD.In India a metaanalysis conducted by Venkatasamy et al[2] in 1998 showed 2.2% to 3.3% for manic depression.
BPAD usually occurs in between 18 and 24 years of age in both men and women , though it can occur in all ages.
It is diagnosed using operationalised criteria – Diagnostic and statistical manual – IV or ICD 10. BPAD can cause dramatic swings in mood – from manic ,hypomanic to depressive mood with inter-episodic normal or euthymic mood. But variance in the intensity of symptoms is seen from one individual to other individual.
There are many types of BPAD based on intensity of prevailing mood during a particular episode. BPAD I is characterised by recurrent episodes
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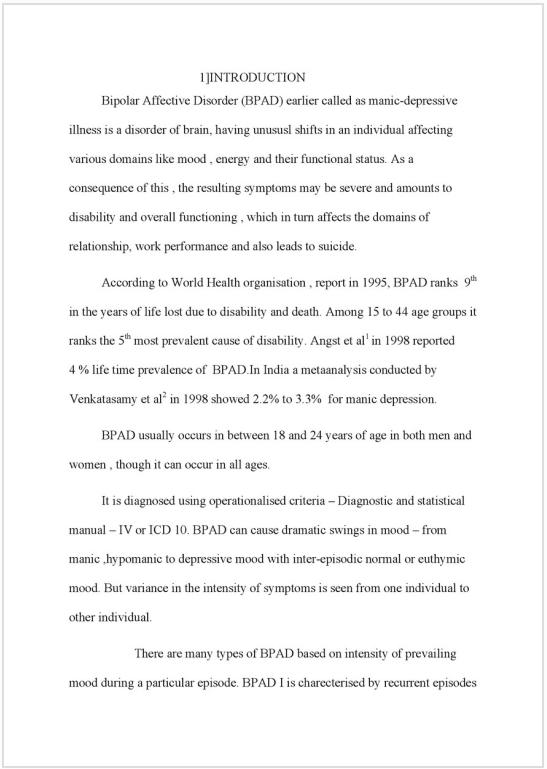

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CONTENTS

ABBREVATIONS

BPAD	-	Bipolar affective disorder
QOL	-	Quality of life
DSM-IV	-	Diagnostic and statistical manual . fourth edition
ICD-10	-	International classification of disease – 10th edition
WHO	-	World health organisation
ISBD	-	International society for Bipolar disorders
PSQI	-	Pittsburgh Sleep quality Index
SWS	-	Slow wave sleep
NREM	-	Non rapid eye movement sleep
REM	-	Rapid eye movement sleep
EEG	-	Electro encephalogram
EOG	-	Electro oculogram
HDRS	-	Hamilton depression rating scale
YMRS	-	Young mania rating scale
WHOQOL-BREF	-	World Health organization Quality of life scale – brief version
HRQOL	-	Health related quality of life
OPQ	-	Occupational performance questionnaire
Q-LSES-Q	-	Quality of life enjoyement and satisfaction questionnaire
MDD	-	Major depressive disorder
SADS	-	Somatic anxiety and depression scale – patient health questionnaire
IIRS	-	Illness Intruvsiness rating scale
SF-12,36	-	MOS short form -12 , 36

INTRODUCTION

Bipolar Affective Disorder (BPAD) earlier called as manic-depressive illness is a disorder of brain, having unusual shifts in an individual affecting various domains like mood, energy and their functional status. As a consequence of this, the resulting symptoms may be severe and amounts to disability and overall functioning, which in turn affects the domains of relationship, work performance and also leads to suicide.

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normal or euthymic mood. But variance in the intensity of symptoms is seen from one individual to other individual.

There are many types of BPAD based on intensity of prevailing mood during a particular episode. BPAD I is characterised by recurrent episodes of mania and depression. BPAD II have milder episodes of high mood – hypomania alternating with depression. Rapid cyclers are those who experience four or more episodes within a year. Some experience within a month or within a week or day and are classified accordingly.

Any episode, depressive or manic is preceded by 1 or 2 weeks of disturbance in sleep activity cycle, goal directed activity, cognitive or affective function. But this pattern varies from individual to individual but is mostly always same in the individual.[3] Thus it is apt to identify this type of prodrome where we can develop preventive steps, to prevent from impending episode, which in turn reduce rates of relapse.[4]

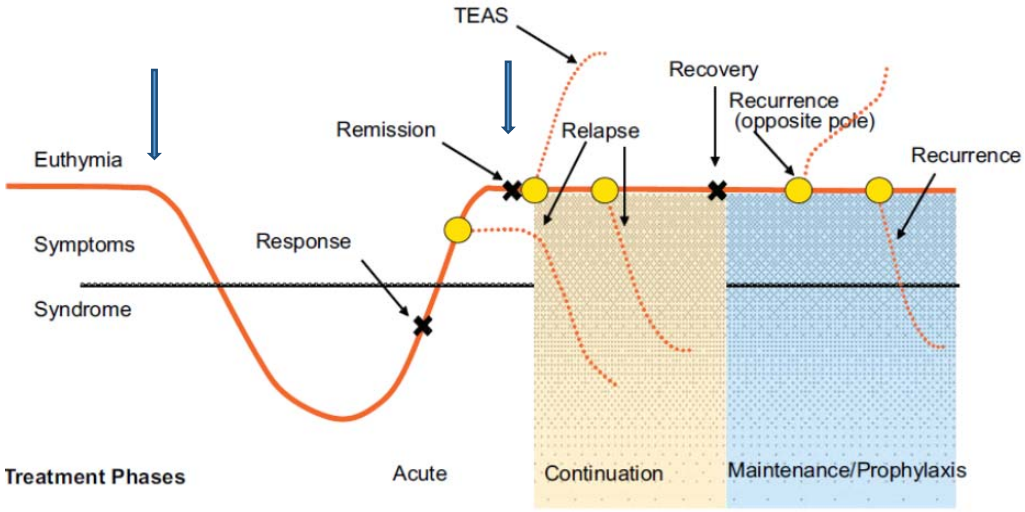
To assess the patient's clinical course, there are clinical definition for defining remission and various quantifying rating scales are used to assess the course in the patient when they are in treatment. One such definition by APA (2002) about remission is "a complete return to baseline level of functioning and virtual lack of symptoms"

This in turn can be measured by clinical rating scales. That is a score of $\leq$ 12 in the YMRS (Young Mania Rating scale) defines

remission in some literature and some use less than four for defining absolute reduction in symptoms. With regards to HAM-D (Hamilton Rating scale for Depression), ≤ 7 is considered remission.

The following figure 1 depicts the various phase of treatment in BPAD. (as adopted from Frank et al .)[5]

FIGURE 1.



A more practical way of defining remission adopted in DSM-IV and ICD-10 (World Health Organization; American Psychiatric Association),[6, 7] states interval of at least 8 weeks remission in between episodes, without any regard to treatment. This means after 8 weeks there is complete symptomatic remission. The time criteria for phase of continuation therapy as per International Society of Bipolar Disorder (ISBD) suggested, 4 weeks for previous manic episodes and 8 weeks for previous depressive episodes (Tohen et al. 2009a)[8], taking into account

that mania and depression takes different course in recovery (Solomon et al. 2010)[9]. Calabrese et al. in 2006 gave a more conservative estimate, setting a cut-off point of 90 for mania/hypomania and 180 days for bipolar depression.[10]

Though theoretically Euthymia or BPAD in remission as per diagnostic criteria does not contemplate any symptoms, recent evidences focus on the significant impairments of BPAD patients in relation to sleep dysfunction, global function reduction and worse QOL (Quality of life) even though they are euthymic.

There are only sparse studies regarding the Sleep quality and QOL in BPAD patients. Harvey et al., studied recently Quality of sleep using actigraphy and Quality of sleep Questionnaire – Pittsburgh Sleep Quality Index (PSQI) with few patients.[11] And regarding Quality of Life though there are enough literature internationally, the methods used to measure were different and not uniform in all studies. Most of all there is only few Indian literature regarding Quality of Sleep and life in BPAD patients. This effort is in that direction and to imply the findings in our day to day clinical practice in monitoring and improving the Sleep and QOL in BPAD from Clinician point of view.

REVIEW OF LITERATURE

Bipolar disorders earlier known as manic – depressive psychosis consists of atleast one hypomania, manic or mixed episodes[12].In between the episodes, there is inter-episodic period of remission or euthymic state.

It leads to severe dysfunction in social, occupational and interpersonal adjustments. There is more evidence to suggest that BPAD patients experience reduced functioning and well-being during interepisodic periods, while an acute episode gets over.[13]

Conventionally treatment of BPAD focuses on acute stabilization, goal being to achieve a symptomatic recovery with euthymic (stable) mood and on maintenance, in which the main aim is to prevent relapse and lessening the subthreshold symptoms and enhancement in functioning of occupational and social domains.

In recent literatures we find that BPAD patients even in remission have a worse QOL and reduced functioning and global domain, thereby leading to poor prognosis.[14]

Globally BPAD patients both type I and II have prevalence of 2% with another 2 % adding on to subthreshold symptoms.[15, 16]

The burden of disease globally, a comprehensive assessment of mortality and disability from diseases and injuries in 1990 and projected to 2020, highlights the importance of mood disorders for the world.

Disability – adjusted life years is based on both mortality and disability. If disability is taken alone, then Bipolar disorder is the sixth leading cause of disability.

The most common age of onset are the teenage years and the prevelance in males and females is similar, in contrast to major depression, where female excess is found.[17]

There is more evidence in literature that sleep disturbances is frequently observed even when BPAD patients are in remission.[18]

Euthymia:

Euthymia is defined as a state pertaining to a normal mood in which the range of emotions is neither depressed nor highly elevated.[19]

In clinical trials, euthymia in Bipolar disorder is conventionally defined as scores below a certain threshold, but never zero in HRSD and YMRS scales.[20]

SLEEP

Sleep is a state of decreased awareness of environmental stimuli that is distinguished from states such as coma or hibernation by its relatively rapid reversibility. Stages of sleep according to electrophysiological criteria are Wakefulness –Stage W, Non rapid eye movement – Stage N1, N2, N3 and Rapid eye movement.

ORGANIZATION OF SLEEP

The normal duration of sleep for an adult to function optimally is about 7 to 9 hours of sleep. Short sleepers are those who sleep ≤ 6 hours per night and long sleepers are those who sleep ≥ 12 hours per night for optimal function.

Apart from genes which influence sleep, the other factors which influence sleep are psychiatric disorders, medical disorders and age factors.

A Healthy adult spends

Stage N1 – 5 % of total sleep period

Stage N2 – 50% of total sleep period

Stage N3 – 20 – 25% of total Sleep period

Stage R – 20 – 25% of total sleep period

NREM and REM sleep occurs in cycles which last for 90 – 110 minutes each.

Slow wave sleep (SWS – stage N3) is seen prominently , mainly during the first period of NREM and wanes of as night progresses .As slow wave sleep wanes, REM sleep lengthen, which shows greater activity and have more intense dreaming.[21]

Monitoring Sleep

Hans Berger in 1929 first reported sleep – wakefulness related changes in human EEG. In addition to EEG, EMG and EOG are used to measure muscle activity and eye movements respectively, to distinguish wakefulness and stages of sleep.

Sleep stage scoring helps us to quantify the sleep and also quality, serving as a more relevant marker clinically of sleep and psychiatric disorders.

Sleep latency – time elapsed from the start of the recording to the onset of any stage of sleep.

REM latency – time elapsed from sleep onset to the first epoch of stage R sleep.

Total sleep time – cumulative time spent in all sleep stages.

Sleep efficiency – how much of the total recording time was spent in any stages of sleep.[22]

Objective measures

Polysomnography – gold standard method to measure sleep variables

Actigraphy – measures the inactivity (Sleep) and activity patterns and also the variability in sleep- wake patterns over several consecutive days.[23]

Variables measured in objective measures

Multiple Sleep Latency test (MSLT) – measures the propensity to fall asleep

Maintenance of wakefulness test (MWT) – measures the ability to maintain wakefulness.[24]

Subjective Questionnaires:

Pittsburgh Sleep Quality Index (PSQI) – assess sleep quality and disturbances over 1 – month time interval.[25]

Measuring Daytime sleepiness

Daytime sleepiness manifests as an increased propensity to fall asleep and/or a decreased ability to maintain wakefulness.

Subjective Questionnaire for daytime sleepiness:

Stanford Sleepiness Scale (SSS) – rate the current level of sleepiness

Epworth Sleepiness Scale (ESS) – rate the individual's probability of falling asleep under various circumstances.

Comparision between objective and subjective sleep measures:

Actigraphy has been validated against polysomnography in Bipolar affective disorder subjects for several sleep parameters, including sleep onset latency, awakening after sleep, total sleep time, and sleep efficiency.[26] More subjective assessments can use sleep / circadian questionnaires such as Pittsburgh Sleep Quality Index (PSQI) which was first developed to assess sleep quality in patients with mood disorders and in patients with sleep disorders.[27] When used in samples of Bipolar affective disorder subjects in remission, it showed a high frequency of abnormalities, and in particular with respect to sleep latency and sleep efficiency.[28] A study conducted by Geoffroy et al., a external validity study concluded that phase preference and sleep duration could be satisfactorily assessed using PSQI. While Polysomnography and actigraphy cant be used in large scale cohorts, sleep and circadian research in Bipolar affective disorder subjects could benefit from a more systematic use of the PSQI in clinical assessments since they are more easily implementable.[29]

SLEEP IN BIPOLAR AFFECTIVE DISORDER PATIENTS:

Sleep is an active state which maintains our emotional, mental and physical wellbeing and is essential for maintaining brain plasticity.[30] Sleep is considered most essential for optimal functioning of cognition

and overall functioning. Sleep dysfunctions affect nearly 20% of the general population including daytime functioning.[31]

Apart from physical conditions leading to Sleep disorders, psychiatric conditions like anxiety disorders, psychoses and mood disorders also coexist with sleep disorders. Theoretically sleep- wake disturbances are the core feature of BPAD patients and most frequent complaints by these patients are circadian rhythm instability.[32]

A part of criteria for diagnosing BPAD has disturbance in sleep – wake cycle i.e., mania characterized by need of decreased sleep and depression by either hypersomnia or insomnia.[33]

Sleep in depression:

Insomnia or daytime sleepiness is reported by up to 90% of patients who have major depression and is among the set of diagnostic criteria for this disorder.[34] Sleep-related findings in patients who are depressed include difficulty falling asleep, difficulty staying asleep, early morning awakening, nonrestorative sleep, fatigue, daytime sedation, increased awakenings, short rapid eye movement(REM) latency, increased percentage of the night spent in REM sleep, and diminished amount of slow wave sleep.[35, 36, 37]

Antidepressants without any sedating properties are used to treat depression which co- occurs with insomnia, where sleep resolves in majority cases.[38]

Sleep in mania:

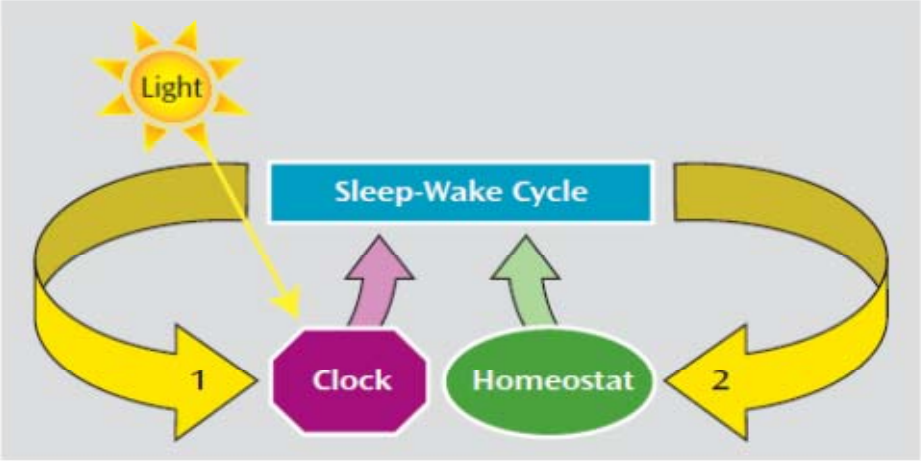
In mania 80% of the patients have sleep disturbance.[39] Unlike depressed patients, who tend to report a lack of restoration from sleep, in mania there seems to be decrease in the ability and need for sleep. Contrary to the tendency to think of insomnia as somehow opposite of depression, the sleep of manic patients also is marked by a slow wave sleep, shortened REM latency, and relative increase in percentage of REM.[40] In mania, increasing the sedative potential is the main aim of treatment.[41]

An effective antidepressant sleep deprivation helps us to understand the relationship between mania and sleep. But the more relapses even after recovery sleep, paves way in research of sleep with genetics, therapeutics and neurochemistry.[42]

There is literature showing BPAD patients with homozygous long variants of serotonin transporter 5-HTTLPR responds more than short variant of hetero or homozygotic.[43]

APA's in its practice guideline on treatment of BPAD[44] lists sleep deprivation as a novel method using this as a prolongation of antidepressant response is the area of research in using it as somatic therapy.[45]

FIGURE 1. Components of the Sleep-Wake Cycle[a]



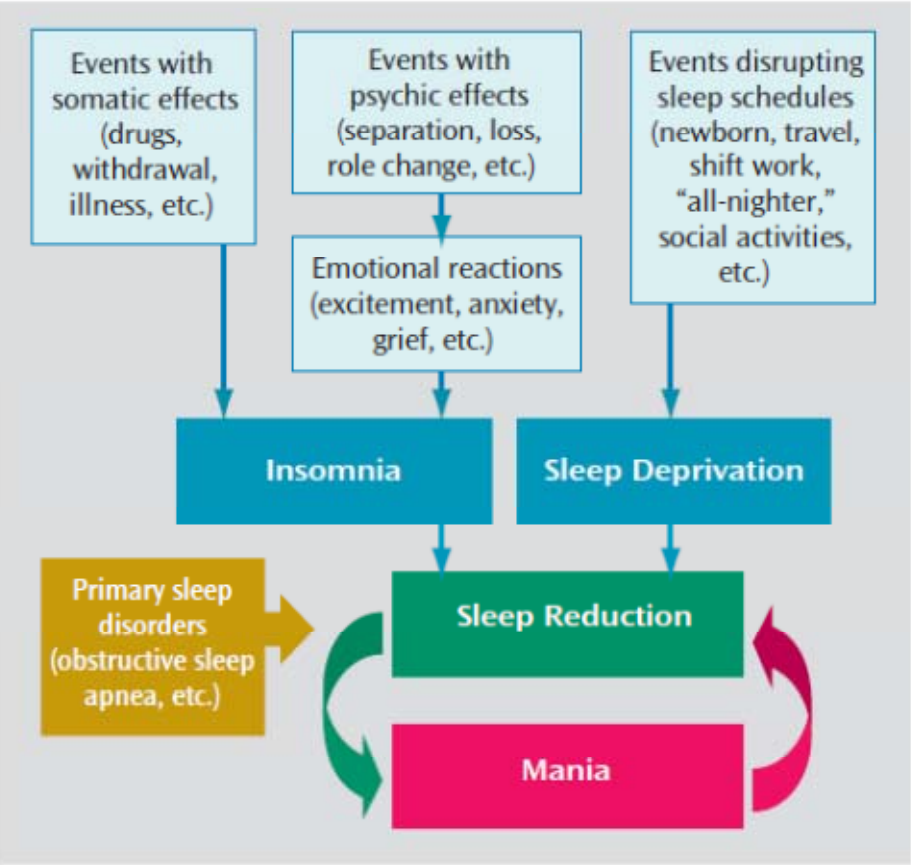
Among patients with depressive BPAD patients we either see insomnia or hypersomnia along with increased sleep duration during night times and awakening difficulties and excessive daytime somnolosence.[46] Jackson et al. points out that sleep disturbance is a prodrome commonly seen in mania and depression.[47] Thus, sleep disturbance is related with recurrence of illness. Some of the studies by Colombo et al . Kasper and Wehr et al. shows that when we induce sleep deprivation as a experimental measure it worsens the depressive and manic symptoms severity.[48]

But the study by Barbini et al. shows improvement of symptoms.[49]

In a study with bipolar affective disorder I patients, the author has pointed out that short sleep duration predicted greater depressive episodes but not for mania.[50]

Spontaneous sleep deprivation marks the start of manic episode, because of hyperactivity, which in turn results in increase in manic symptoms and subsequently leading to sleep loss.[51] Thus sleep loss contributes as both triggering and augmenting factor and thereby leading to worsening of symptoms.

FIGURE 3. Sleep Reduction as a "Final Common Pathway of Mania," Revisited[a]



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Sleep loss in BPAD patients leads to mood episode onset in the subsequent 24 – hour period and the intensity of sleep loss directly correlate with change of mood. [53]

Sleep abnormalities in depression and mania [54]

Patients complaints	PSG findings
Insomnia Initial insomnia Middle insomnia Terminal insomnia	Disturbance in sleep continuity Increased latency of sleep onset High wake time during sleep Total sleep time decreased
Less Sleep duration Less satisfying or deep sleep	Slow Wave Sleep (SWS) deficits SWS duration is less Less SWS % of total sleep
Dreams which are disturbing	Abnormalities in REM sleep less REM sleep latency Prolonged first REM sleep period Increased REM activity (total No. of eye movements during the night) Increased REM density (REM activity /total REM sleep time) Increased REM sleep % of total sleep

Sleep in euthymic (remitted) BPAD patients:

Along with more suffering and worst consequences in episodes, we see even the patients in remission have persisting symptoms. Literature says nearly 50% of the patients in euthymia will again have another episode in a two year period.[55] Even though there is advances in psychological and pharmacological treatments, the risk of inter – episode

dysfunction and relapse remains high. Harvey et al. points out that nearly 70% of euthymic BPAD patients exhibit clinically significant sleep disturbance. [56] In addition to that Millar et al. shows that remitted bipolar affective disorder patients, when compared to healthy controls has longer sleep duration and greater sleep variability.[57] There is also some literature stating that euthymic BPAD patients have unstable circadian rhythm persistently.[58] They also show low day time activity levels and nocturnal insomnia, an important impairment of sleep related functioning.[59]

In a study conducted by Rocha et al., in 2013 with 94 BPAD I and 11 BPAD II subjects in a tertiary care setting, comparing with 104 healthy controls showed mean age group of 47 (SD=18.5) and 77.1 % were females, matched for age and sex with Healthy controls . He used PSQI as the sleep measures. And the entire sample was on medications either Antipsychotics, mood stabilizers or lithium. He concluded that BPAD patients scored significantly higher than healthy controls in PSQI scores.[60]

In another study conducted by Walz et al., in 2012 in a similar setting, with age and sex matched controls, using PSQI and ESS, where medication taken were not reported. Here also the Bipolar Affective disorder subjects scored significantly higher in both PSQI and ESS scores.[61]

In a longitudinal study conducted by Katherin et al. around 25% of BPAD patients in remitted state, in contrast to baseline symptoms of depression and on treatment show hypersomnia, indicative of impending depressive episodes in future.[62]As pointed out by Joffe et al [63]patients in the inter- episodic interval spend nearly half of the time unwell, which in turn predict future relapse into mania or depression.[64]

Though the exact determinant of the disorder remain unclear, pathophysiology is partly linked to sleep and circadian disturbances.[65] According to social zeitgeber theory, in vulnerable individuals irregular circadian rhythm leads to mood episodes.[66]

In part, high frequency of subsyndromal inter episode symptoms are characterized in BPAD subjects.

Millar et al. observed sleep in 19 euthymic bipolar I patients matched for age and sex with controls using sleep diary and actigraphy. He found that euthymic BPAD subjects had greater latency of sleep onset, duration of sleep is increased, and more variable night to night sleep patterns.[67]

Harvey et al. used PSQI and Actigraphy to compare 20 BPAD in remission subjects with 20 patients with primary insomnia and equal number of controls. He stated that sleep status of the euthymic BPAD group did not differ from insomnia group but not so with controls. 70% of the remitted BPAD patients had poor sleep quality according to the

Pittsburgh Sleep Quality Index assessment. Actigraphic studies estimated that, euthymic patients compared with controls show increased latency of sleep onset, daily activity was below average, and sleep– wake cycle is fragmented mostly with more variability from night-to-night . Compared with other groups, BPAD in remission subjects had diminished sleep efficiency, more fear and anxious about sleep, tendencies to mis-percieve sleep, with some abnormal beliefs about sleep.[68]

In a study conducted by Paulo et al., using PSQI – BR poor sleep quality is noted in 82.9% of euthymic BPAD as against 21.2% of the control group (P = 0.000). Though the subcomponent, shows comparable results in sleep duration (P = 0.535), the other components like sleep latency showed significant disruption (P 0.000) and sleep efficiency (P 0.000) was decreased when compared to controls.

Some of the following studies showed conflicting results. Knowles et al. observed the sleep pattern in euthymic BPAD patients who were compared with age matched controls. He did polysomnography for 10 euthymic BPAD subjects for a period of five nights. There were no significant differences except for more frequent arousals in subjects.[69]

Sitaram et al. observed REM density and % of REM sleep is increased in euthymic bipolar subjects when compared to healthy subjects.[70]

Jones et al. compared circadian activity patterns in bipolar subjects and healthy controls. He found that BPAD subjects showed that the activity during daytime is highly variable, but regarding latency of sleep onset and other sleep parameters did not show much significance.[71]

There are only limited studies in this aspect. Although the results are conflicting, BPAD subjects in euthymic phase do exhibit sleep disturbance which leads to further episodes of illness as discussed earlier.

QUALITY OF LIFE

IT is not merely good health, but more than that and is difficult to explain easily. There is no uniform definition to describe QOL. There are only few studies regarding QOL in BPAD patients.

QOL concept was first used by Ordway and Fairfield Osborn (American Economist), regarding concern over uncontrolled economic growth.

Since 1960, social scientists began to use this term QOL and observed a very positive and stable relationship between social indicators and QOL.

Calman in 1984 defined QOL as the relationship between a person's expectations and achievements. While there is no consensus regarding correct concept of defining, many would agree that QOL is

a) A multidimensional construct, with all aspects of psychological, social and physical wellbeing b) Rather than a professionals view it is more of patients own subjective evaluation. The problem of describing QOL is frequently been solved by taking a "psychometric short-cut" by operating the construct as a score on a questionnaire or set of scale.

Assessment of various domains of daily functioning like physical, mental and social is carried out based on patient's self report.

It is important to take note that the term subjective, doesn't mean soft or unreliable, as opposed to objective as is often assumed but it is referring to the source of information.

Subjective Data can be obtained using reliable, objective methodologies for that purpose.

The term QOL in psychiatry refers to the body of research work on psychological well-being, life satisfaction, emotional functioning, social support, etc. Initially, within the field of psychiatric research, the important intention of QOL assessment had been on the symptoms, impairments and disabilities of severely mentally ill persons. Since the early 1980s, there was an attempt to go for the disease models for these disorders and the majority of the new measures have been based on the perspective of general health QOL.

QUALITY OF LIFE AND BIPOLAR DISORDER

BPAD is associated with impairment in functioning with significant disability. According to W.H.O Bipolar disorder is the 6 th leading cause of disability among young adults worldwide.[72] For example, if a woman develops BPAD in her 30's, 9 years of life expectancy is lost to her mainly due to medical and cardiac problems, productivity loss of fourteen years, and loss of twelve years in good health.[73] Lifetime rates of suicide in BPAD Bipolar disorder whether a treated patient or not is estimated to be 15 %.[74]

While outcomes in patients with BPAD outcomes are generally assessed objectively by rates of relapse, number of inpatient admissions, reduction in symptoms assessed by rating scales by clinician traditionally, there is more view point about adding QOL (quality of life) and functional measures.[75] It has been observed clinically functioning does not correlate with severity of symptoms, whether less or more symptoms.[76] QOL relatively lags behind symptomatic remission and there is evidence for the same.[77] Thus moving towards a wide set of outcome measures, like that in schizophrenia research, biopsychosocial model is proposed, thereby leading to efficacious adjunctive treatments in psychosocial aspects.[78] So we see an urge of expanding therapeutic targets where more contributions is from the psychosocial aspect.[79]

As asserted by Harvey, for example: "recovery should not be defined merely by symptomatic remission or even syndromal remission; rather, recovery should include symptomatic recovery, syndromal recovery, functional recovery, and a return to an acceptable quality of life for the patient."[80]

Education, occupation, medication side-effects, environment, physiological domain, health care facilities, leisure time activities, sexuality and daily routines all contributes as factors influencing QOL. On the contrary, many patients were doing exceptionally admiring inspite of the diagnosis leading for new opportunities in life. But it is described by those patients, that it took many hardships to get back on track.[81]

Based on Kraepelin's work, held that schizophrenia and manic-depressive disorder differ mainly in cognitive impairment and life events and QOL, where the latter did not get affected much.

Literature shows evidence that 1/3rd of subjects have intellectual and social dysfunctions even in euthymic period, thereby affecting their level of functioning and well –being studies.[82]

Due to the cyclical nature of BPAD, remissions and exacerbation of symptoms directly affect one's emotional, social, physical and functional well-being. However, the conceptual model declares subclinical symptoms affect QOL considerably.[83] A recent literature review on BPAD-quality of life [84] came up with 4 groups:

1] Studies comparing BPAD patient QOL with that of schizophrenic patients and patients with unipolar depression.[85]

2] Different subgroups BPAD patients within themselves[86, 87, 88]

3] Evaluating the different characteristics of the instruments used for measuring QOL[89, 90, 91, 92] and

4] Comparing the QOL of different BPAD subgroups and evaluating instrument characteristics[93, 94]

VARIOUS STUDIES ASSESSING QOL IN REMITTED (EUTHYMIC) PATIENTS WITH BIPOLAR AFFECTIVE DISORDER

Sierra et al. (2005) used SF-36, CARS-M and HDRS to evaluate the QOL in BPAD subject under remission and all the subscales Score in SF-36 were low in patients than control.[95]

Gazalle et al. (2006) used WHOQOL-bref scale to assess the QOL in bipolar- and bipolar remitted patients showed that higher domains score were reported for the remitted patients compared to lower score for the depressed patients.[96]

Mania et al. (2007) compared HRQOL between Bipolar Disorder type I and II in euthymic patients. SF-36, HDRS and Young Mania Rating

Scale (YMRS) were used for the evaluation. The result of the study stated that type II was associated with poor QOL compared to type I even after long periods. Interventions might improve functional enhancement.

Kusznir et al., (2000) from Canada assessed the correlates of community functioning in 61 euthymic BD patients comprising of 47 type I and 14 type II BD patients using OPQ (Occupational Performance Questionnaire). He concluded that 1/3rd of sample did not function well in the community. The limitation of the study is cross-sectional research design.[97]

MacQueen et al., (2000) from Canada studied the Effect of number of episodes on wellbeing and functioning of subjects with BPAD in 64 euthymic type I BD using SF-20. He concluded that No. of previous depressive episodes a stronger determinant of HRQOL than No. of previous manic episodes. The limitation of the study was number of previous episodes were determined retrospectively.[98]

Chand et al in India compared Quality of life in 50 Bipolar Affective disorder subjects in remission with 20 subjects with schizophrenia and 20 controls using Q-LES-Q, WHO-QOL-BREF. He observed that patients with BPAD had better QOL than subjects with schizophrenia but more or less same QOL to control groups. Limitation

of the study is matching was incomplete among groups ; low Q-LES-Q scores seen in control group.[99]

Cooke et al., from Canada studied QOL In 68 BPAD subjects in remission in which 55 were type I and 13 were type II with SF-20.He observed that SF-20 scores were not different from Major depressive disorder groups. BPAD type II patients reported poorer HRQOL that BPAD type I. The Limitation was shortcomings of SF-20 when it is compared with

SF-36.[100]

Dogan et al., (2003) from Turkey assessed the QOL in 26 outpatients with BD stabilized on lithium. He used WHO-QOL-BREF for the same. He observed significant improvement in general health, physical functioning and social functioning 3months after a psychoeducation intervention. The main limitation of the study was small sample size.[101]

MacQueen et al., (1997) from Canada studied the Levels of functioning and well being in recovered psychotic versus nonpsychotic mania. He observed in 62 type I euthymic BD patients, He used SF-20 for assessment. He conclude that there were No significant differences in SF-20 scores between psychotic and non-psychotic patients. The limitation of the study is small sample of patients with psychotic symptoms.[102]

Ozer et al., (2002) from Turkey observed Outcome measures of interepisode bipolar patients in a Turkish sample of 100 interepisode BPAD patients using Q-LES-Q. He concluded that Depression scores on SADS interview significantly predicted lower Q-LES-Q scores. The limitation of the study is cross-sectional nature of research.[103]

Robb et al., (1997) from Canada studied Quality of life and lifestyle disruption in 68 euthymic bipolar patients (55 type I, 13 type II) using IIRS. He observed that Greater illness intrusiveness associated with higher Ham-D scores, recent depression and BD type II. The limitation of this study is IIRS not validated for use in BD populations.[104]

In another study Robb et al., (1998) observed whether Gender differences in patients with bipolar disorder influence outcome in the medical outcomes survey (SF-20) subscale scores in 69 euthymic BD patients (54 type I, 15 type II) . Women possessed significantly lower SF-20 scores in the domains of pain and physical health. The Limitation of the study is shortcomings of SF-20 as a HRQOL measure.

Vojta et al., (2001) from US studied 86 BD patients (16 manic/ hypomanic, 26 MDD, 14 mixed, 30 euthymic) using SF-12 and EuroQoL. He concluded that SF-12 mental health scores were significantly lower in manic group than in euthymic group. MDD/ mixed group SF-12 scores were significantly poorer than in manic/euthymic groups. The limitation were small sub-samples, brief nature of the SF-12.[105]

AIMS AND OBJECTIVES

AIM

To assess the quality of sleep and quality of life in Bipolar affective disorder subjects under remission

OBJECTIVES:

Primary objective:

1] To compare quality of sleep between Bipolar affective disorder subjects under remission with age and sex matched Healthy controls.

2] To assess the quality of life in Bipolar affective disorder subjects under remission in comparison with age and sex matched controls.

Secondary objectives:

1] To assess various clinical variables with Quality of sleep and Quality of life.

2] To compare quality of sleep with quality of life.

HYPOTHESIS

Null hypothesis

There is no significant difference in QUALITY OF SLEEP and QUALITY OF LIFE between Bipolar Affective Disorder subjects under remission and healthy controls.

Alternate hypothesis

There is significant difference between the quality of sleep and quality of life between Bipolar affective disorder subjects under remission and healthy controls.

MATERIALS AND METHODS

SETTING

The Study was carried in Institute of Mental Health, Madras Medical College, Chennai, a tertiary referral centre catering the whole population of Tamilnadu. The necessary prior permission for conduct of the study was obtained from Institutional Ethics committee, Madras Medical College, Chennai.

STUDY POPULATION:

Bipolar Affective disorder Subjects (BPAD) who are in remission attending the Outpatient clinic in Institute of mental Health. Healthy Controls were selected from the community and from persons visiting the hospital inquiring the good will of patients.

SAMPLE SIZE:

A total sample size of 100 with 50 each in BPAD subjects under remission and 51 Healthy controls matched for age and sex was collected.

SAMPLE SIZE CALCULATION:

When we calculate sample size for this present case control study, with 95% two sided confidence interval 1 – alpha, with 1:1 ratio of controls, with proportion of cases with poor sleep quality of 63.4% and

proportion of controls[106] with 20% with extreme odds ratio of 7.00 we arrived at a sample size of minimum 35 in number in each cases and controls, using SPSS software version20.0 / openEpi

PERIOD OF STUDY :

The Study was conducted for a total duration of 6 months from April 2015 to September 2015.

SAMPLING METHOD :

Consecutive Sampling.

RESEARCH DESIGN:

CASE CONTROL STUDY:

One hundred and one subjects participated in the study, 50 in Bipolar affective disorder subjects in remission and 51 in healthy controls matched for age and sex who were free from any major medical or psychiatric illness, recruited from the community and from the workers in the hospital.

INCLUSION CRITERIA:

1] All subjects who met the criteria for BPAD according to Diagnostic and Statistical manual fourth edition (DSM-IV) or

ICD-10, qualifying for remission, last episode at least 6 months earlier.

2] Age group from 18 – 60 years old.

3] Willing to give written informed consent for participation in the study. [Annexure]

EXCLUSION CRITERIA :

1] All subjects who have major co morbid psychiatric illness

2] Substance use disorder in dependence level in history.

3] Subjects having co morbid medical and surgical illness

4] Age less than 18 and more than 60 years.

5] Subjects not willing to give informed consent.

OPERATIONAL DESIGN:

After written informed consent was obtained from the participants, as required by Institutional ethics committee who approved this study, All subjects with Bipolar affective disorder as per DSM IV or ICD – 10 were administered MINI-Plus to rule out other co morbid psychiatric illness. They were then quantified for remission[107] (euthymia) by using Hamilton depression rating scale (HAM-D) and Young mania rating scale (YMRS) with HAM-D score <7 and YMRS score < 4, who have rich previous

medical records in our tertiary care hospital quantifying for severity with the above scales when an episode occurred and followed up with the above scales and were recorded as patients under symptomatic remission. And those who have achieved the remission 6 months earlier by these quantifying scales were taken in this study, and also quantifying while entering the study.

The study was done in a single setting, and all the relevant details were got from subjects, and their informants along with medical records.

They were administered the following questionnaire regarding their Quality of sleep and quality of life both semi-structured and structured form.

The healthy controls were matched for age and sex, and any current or past history of psychiatric illness were ruled out using MINI-Plus structured questionnaire. They were also administered semi-strucured questionnaire and structured questionnaire as follows in a single setting.

The instruments used are :

- **MINI-Plus structured clinical interview**
- **Semi-structured questionnaire**

- **Hamilton depression rating scale**
- **Young mania rating scale.**
- **Pittsburgh Sleep Quality Index.**
- **Epworth sleepiness scale.**
- **World Health Organization Quality of Life (WHOQOL)-BREF**
  -Tamil version

MINI – PLUS structured clinical interview: (Annexure)

The MINI – PLUS is a brief structured interview to rule out Axis I psychiatric illness as per DSM IV and ICD-10, which include 23 disorders in it. The advantage is it can be administered in a shorter period in time with a median of 15 minutes when compared to SCID-P for DSM III and CIDI (ICD -10 developed for lay interviewers by W.H.O), with which it has comparably high validity and reliability scores.

Semi- structured profoma (Annexure)

It was used to collect subject's socio-demographic profiles like age, sex, religion, domicile, education level, occupation, Socio-economic status according to modified Kuppusamy scale, along with clinical variables like duration of illness, age of onset of illness, No. of manic episodes and depressive episodes, suicide attempts and last episode

occurrence. In addition Sleep hygiene questionnaire were also administered for all subjects, both cases and controls.

Hamilton Depression Scale (HAM-D or HDRS)[108]: (Annexure)

This scale was first introduced by Max Hamilton in 1960. It is widely used and accepted in assessment of severity of depression and in follow up guide in recovery. Though the original author does not provide a specific guidelines to administer and rating, it shows a high inter- rater reliability. Several versions of HDRS are available. In HAM-D 21 item version only 17 items are scored and others are taken up for clinical information, like hypersomnia, increased appetite and concentration and indecision. It takes about 20 minute to administer the scale .Eight items are scored from 0 = not present to 4 = very severe and other 9 items are scored from 0 to 2.

Normal	**Mild**	**Moderate**	**Severe**	**Very severe**
0-7	8-13	14-18	19-22	$\geq$ 23

Validity is best when compared with other scales for depression.

Young Mania Rating Scale (YMRS)[109] : (Annexure)

This scale is used to quantify the severity of manic symptoms and in follow up over time with treatment. It consists of 11 items, scored on a

likert scale of 0 to 8 for four items and 0 to 4 for 7 items. Reliability is good based on inter – rater reliability and consistency studies.

PITSBURGH SLEEP QUALITY INDEX[110]: (Annexure)

It is used to measure sleep disturbances and sleep habits for the previous month. The questionnaire consists of totally 19 items from which 7 clinical domains of sleep quality are derived. They are

Component – 1 = Sleep quality,

Component -2 = sleep latency,

Component- 3 = sleep duration,

Component -4 = habitual sleep efficiency,

Component -5 = sleep disturbances,

Component – 6 = use of sleeping medications, and

Component – 7 = daytime dysfunction

The subjects self rate the questionnaire in a3 point Likert scale where 3 indicates negative extreme of the component scored. It has a good test – retest reliability correlation coefficient = 0.85 and internal consistency (Cronbach's alpha 0.83). Concurrent validity and discriminative validity is comparable with the clinical evaluation, sleep questionnaires, other questionnaires. It was developed by Bussye DJ .A score of >5 has a diagnostic sensitivity of 89.6% and specificity of 86.5%

to distinguish “poor” sleepers (cases) from “good” sleepers (healthy subjects).

Epworth sleepiness scale(ESS)[111] : (Annexure)

The ESS is widely used in sleep medicine as a subjective measure of daytime somnolescence. It consists of 8 situations in which tendency to become sleepy is rated . 0= no chance of dozing, to 3= high chance of dozing. It derives score whether a medical attention is needed for daytime somnolescence are needed are not.

Interpretation:

0-7: Unlikely to be abnormally sleepy.

8-9: An average amount of daytime sleepiness.

10-15: Excessively sleepy .Needs medical attention.

16-24: Excessively sleepy and consider seeking medical attention.

World Health Organization Quality of Life (WHOQOL)-BREF[112]: (Annexure)

The QOL assessment was made with this scale in a Tamil version with letter of permission from W.H.O – Geneva. It was chosen, as it is generic scale developed simultaneously in 15 field centres including India. It is 26 –item scale and measures four domains.

Physical health Domain – question 3, 4, 10, 15, 16, 17, 18

Psychological Health Domain – question 5, 6, 7, 11, 19, 26

Environment domain – questions 8, 9, 12, 13, 14, 24, 25

Social relationship Domain – questions 20, 21, 22 and

Overall perception of General well being (QOL) – questions 1

Overall perception of Health – questions 2

All questions are scored from 1 to 5 likert scale, with a total score ranging from 26 – 130.

Higher score indicates better quality of life in each Domain. The psychometric properties are in comparison with WHO- QOL-100. Both have a good correlation in the four domains with a value of 0.89 or above. As a whole this scale has good test-retest validity, internal consistency, good discriminate validity and content validity.

Statistical Analysis:

SPSS software version 20 was used to analyse the Data. Descriptive statistics was used for socio-demographic and clinical variable. Independent T-test was used to compare mean values between cases and controls.One –way ANOVA was used to compare means with clinical variables. Chi-squared test was used for categorical variable. Pearson correlation was used for comparing group means, sleep measures and QOL domains. And for calculating the domain values for WHOQOL-BREF SPSS software version 20 was used. All results were interpreted for significance, for P value of < 0.05.

RESULTS AND OBSERVATION

SOCIODEMOGRAPHIC PROFILE:

The sample consists of 50 patients (cases) and 51(healthy controls) who were matched for age and sex, of which 26 males and 24 females were in cases against 27 males and 24 females in controls,who were age-matched denoted as below.

TABLE 6.1 Independent sample T-Test to compare mean age between Cases and Controls (P VALUE < 0.05 IS SIGNIFICANT)

	Group	N	Mean	Std. Dev	t-Value	P-Value
Age (years)	Cases	50	**39. 20**	11. 806	0. 361	**0. 719**
	Controls	51	**40. 04**	11. 560		

AGE:

There was no significant difference (p=0. 719) in age between patients and healthy controls. Mean age of patients was 39± 11. 8 years and controls 40±11.6 years. This denotes Age matched controls. (TABLE 6.1)

TABLE 6.2 Chi-Square test to compare proportions between Cases and Controls

Sociodemographic profile		Cases n=50		Controls n=51		P value <0.05 Sig.
		N	%	N	%	
Genders	Male	**26**	**52. 0**	**27**	**52. 9**	**0. 925**
	Female	**24**	**48. 0**	**24**	**47. 1**	
Marital status	**Single**	**13**	**26. 0**	**5**	**9. 8**	**0. 033**
	Married	37	74. 0	46	90. 2	
Education	Illiterate	3	6. 0	0	. 0	0. 239
	Primary	6	12. 0	5	9. 8	
	Middle	12	24. 0	19	37. 3	
	High	20	40. 0	15	29. 4	
	Graduate	9	18. 0	12	23. 5	
Occupation	**Unemployed**	**12**	**24. 0**	0	. 0	**<0. 001**
	Unskilled	23	46. 0	25	49. 0	
	Semiskilled	12	24. 0	24	47. 1	
	Skilled	3	6. 0	2	3. 9	
Employment Status	**Full time**	**27**	**54. 0**	**51**	**100. 0**	**<0. 001**
	Part time	**9**	**18. 0**	0	. 0	
	Home maker	**9**	**18. 0**	0	. 0	
	Unemployed	**3**	**6. 0**	0	. 0	
	Night shift	**2**	**4. 0**	0	. 0	
Socio Economic Status	Lower	**5**	**10. 0**	**0**	**. 0**	**0. 017**
	Upper Lower	38	76. 0	36	70. 6	
	Lower Middle	**7**	**14. 0**	**15**	**29. 4**	
Language	Tamil	42	84. 0	50	98. 0	**0. 016**
	Others	8	16. 0	1	2. 0	

Religion	Hindu	38	76. 0	41	80. 4	0. 759
	Muslim	4	8. 0	2	3. 9	
	Christian	8	16. 0	8	15. 7	
Domicile	Rural	4	8. 0	0	. 0	0. 067
	Semi-Urban	42	84. 0	43	84. 3	
	Urban	4	8. 0	8	15. 7	
Family History	Mother	0	. 0	2	3. 9	0. 088
	Father	3	6. 0	0	. 0	
	Nil	47	94. 0	49	96. 1	

The significant differences between cases and controls were :

MARITAL STATUS:

13 (26%) patients were single in marital status as opposed to only 5 (9. 8%) in controls. (TABLE 6.2)

EDUCATION:

There were no significant differences. (TABLE 6.2)

OCCUPATION:

Unemployed were 12 (24%) in number of which 9 were homemaker and 3 were unemployed in patients and others were 23 (46%) unskilled and 12(24%) semiskilled and 3(6%) skilled labourers as against the controls in which all were employed ($p < 0. 001$), with equal semiskilled and unskilled labourers and all were full time employed. (TABLE 6.2)

SOCIOECONOMIC STATUS :

According to modified kuppusamy scale, most of them in both patients and controls were upper lower, but there were 5 (10 %) lower lower class and 7(14%) in lower middle in patients as against 15 (29%) lower middle class in and no lower lower class in controls. ($p < 0.017$) (TABLE 6.2)

LANGUAGE:

91% of the samples were Tamil speaking, and all understands Tamil.

There were no significant differences in domicile area, religion followed and family history (though negligible) in both patients and healthy controls.

TABLE 6.3 A] CLINICAL VARIABLES ASSESSED IN BPAD SAMPLES (cases)

	MEAN	**SD**
1] Duration Of Illness (Years):	15.24	9.79
2] Number Of Hospitalisation:	1.96	1.55
3] Age At Onset Of Illness(Years):	24.00	7.51
4] Age Of 1st Manic Episode (Years)	25.56	8.31
5] Age Of First Depressive Episode (Years) :	22.22	16.11

6] No. Of Manic/Mixed Episodes-Nom (N=50) :	3.32	2.36
7] No.Of Depressive Episode-Nod (N=33):	0.92	0.66
8] No Of Rapid Cycle Patients:	0	0
9] LAST EPISODE (MANIC/DEPRESSIVE) OCCURRENCE (MONTHS EARLIER) In Months	41.54	31.04
11] No.Of Attempts (N=9):	0.18	.388
13]Hrsd	1.96	1.70
14]Ymrs	0.800	1.11
15] AVERAGE EPISODE DURATION (AED Or EED)	2.90	1.16

MAINTENANCE PHASE OF CASES:

Among the cases 46 (92%) were on some antipsychotics, 42(84%) on mood stabilizers, 14 (28%) on lithium, and 6 (12%) on antidepressant, and 19 (38%) were on anticholinergic and no cases were on Benzodiazepines. All BPAD patients were in maintenance treatment in remission phase of the bipolar illness. And controls were not on any medications.

SLEEP MEASURES:

When we have PSQI Global score of ≥ 5, we found that 44 euthymic BPAD subjects (88%), and 27 healthy controls (52%) were having poor sleep quality and derived at a 2 × 2 contigency table

TABLE 6.4

	Sleep dysfunctions present(N) (%)	**Sleep dysfunctions absent(N) (%)**	**Total**
Euthymic BPAD	44(88%)	6(12%)	50(100%)
Healthy controls	27(53%)	24(47%)	51(100%)

We arrive at an **Odds ratio of 6.5185** with 95% confidence interval (2.3627 to 17.9843) with P< 0.05. (TABLE 6.4)

TABLE 6.5 Independent samples T-Test to compare mean values between cases and controls (P VALUE < 0.05 IS SIGNIFICANT)

Variables	**Group**	**N**	**Mean**	**Std. Dev**	**t-Value**	**P-Value**
PSQI Global	Cases	50	**9. 54**	4. 132	7. 994	**<0. 001**
	Controls	51	**4. 47**	1. 837		
Epworth Sleepiness Scale	Cases	50	**3. 44**	2. 620	4. 842	**<0. 001**
	Controls	51	**1. 29**	1. 758		

PSQI – If the score is ≥ 5, then the patients have sleep disturbance or poor sleep quality. The mean PSQI score of cases is 9. 54 ± 4. 13 when compared to healthy controls, whose score is **4.47**±1. 83 (P<0. 001).

(TABLE 6.5) Though ESS score shows significant differences between the patients and healthy controls, it is not alarming value for day time somnoloscence. Thus definitely the patients have significant sleep disturbance when compared to healthy subjects.

Following are the individual sleep components of the scale, which shows significant difference between the cases and controls except component – 5 (table 6.6)which, because we have selected healthy controls and patients without any significant medical co morbidities, which will interfere in the sleep- wake cycle and would pose as confounding factor for our study. But this has been excluded and that is why the component-5 which is nothing but Sleep disturbance due to various other causes like pain, snoring etc., But the other components like

TABLE 6.6

PSQI COMPONENT	CASES MEAN(SD)	CONTROLS Mean(SD)	t-VALUE	P-VALUE <0.05 SIG
1]Subjective Sleep Quality	1.44± 0.837	0.47±0.504	7.035	**<0.001**
2]Sleep Latency	1.74±0.828	1.12±0.973	3.459	**0.001**
3]Sleep Duration	0.74±0.899	1.35±0.770	3.682	**<0.001**
4]Habitual Sleep Efficiency	0.92±1.027	0.06±0.238	5.780	**<0.001**
5]Sleep Disturbances	0.88±1.154	0.71±0.576	0.962	0.338
6]Using Medications	2.46±1.054	0.00±0.000	16.506	**<0.001**
7]Daytime Dysfunctions	1.28±0.927	0.76±0.825	2.970	**0.004**

Here, the subjective sleep quality and sleep efficiency are inverse scoring i.e., when the score increases subjects have poor sleep quality and reduced sleep efficiency (Annexure for PSQI scale).Except component 5, which is sleep disturbances due to other causes, other individual components have significant differences between the cases and controls, where Euthymic BPAD cases scores are high in all individual components adding on to the total PSQI score. (TABLE 6.6), (FIGURE 6.1)

FIGURE 6.1

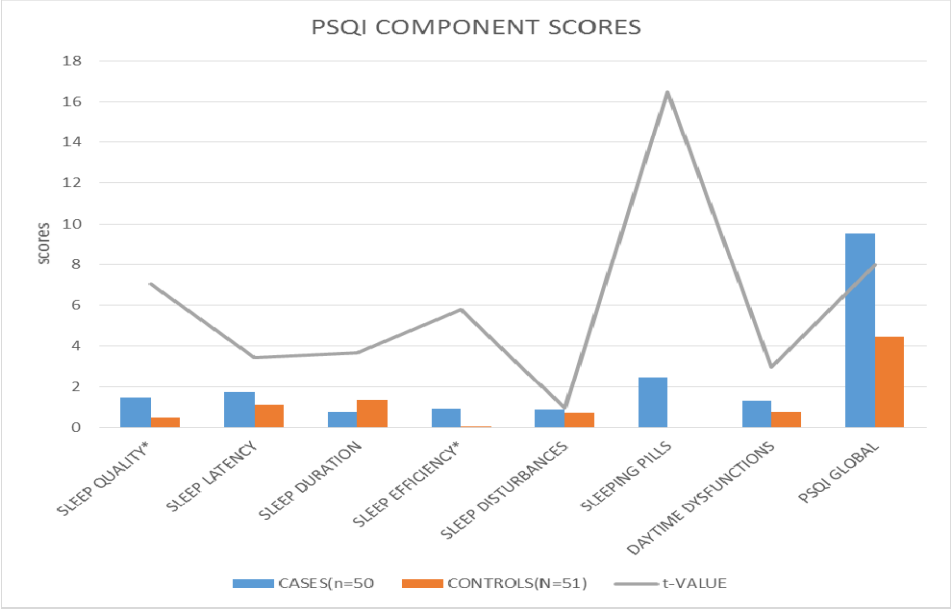
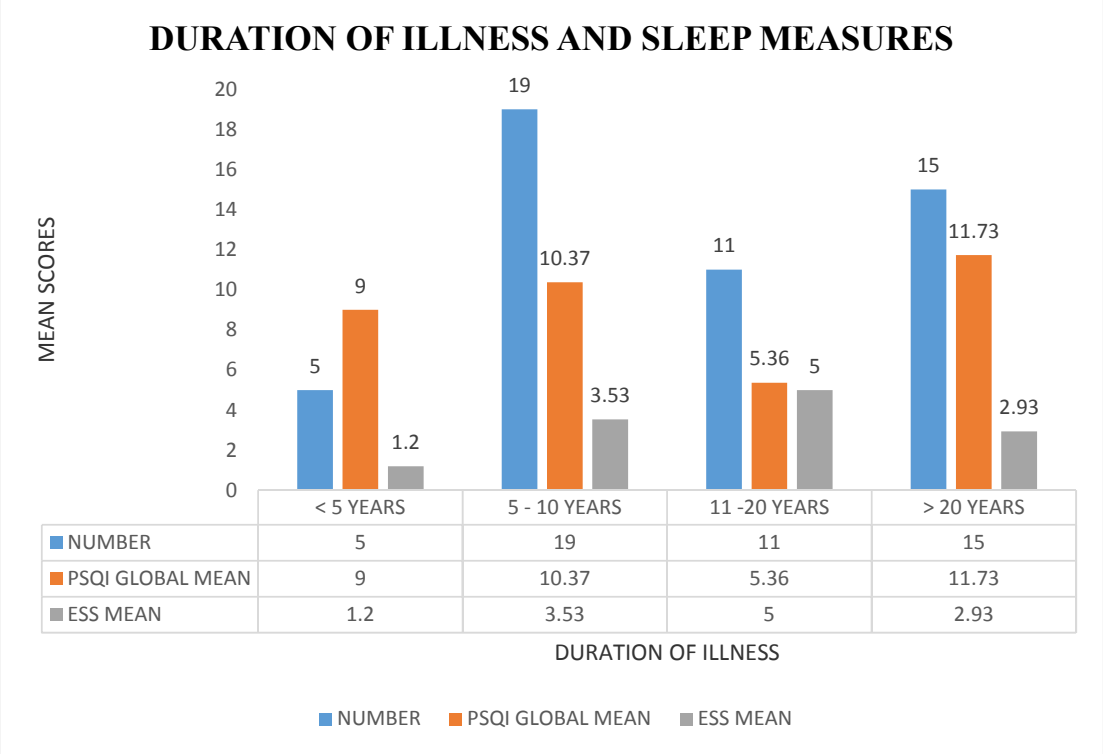


FIGURE 6.2 One way ANOVA to compare mean values between duration of illness



We have divided the duration of illness into 4 groups, < 5 years (N=5), 5 to 10 years (N=19), 11 to 20 years (N=15) .It is seen that the mean PSQI scores shows an increasing trend from PSQI global score mean of 9.00± 1.732 in < 5 years duration of illness to 11.73±4.367 in > 20 years duration of illness(P <0. 001), but with a trough in between when the duration of illness is between 11 to 20 years with PSQI global mean score of 5.36±3.722 .Epworth sleepiness scale also shows increase in the scores but reduction after 20 years of illness(P=0. 038).(FIGURE 6.2) That is Sleep disturbance prevails over the entire period and intensity

is more during 5 – 10 years of illness and > 20 years of illness ie., individual components like sleep latency, sleep duration and habitual sleep efficiency along with daytime dysfunctions are more affected. Which in turn lead to more relapses and subsyndromal sleep disturbances.

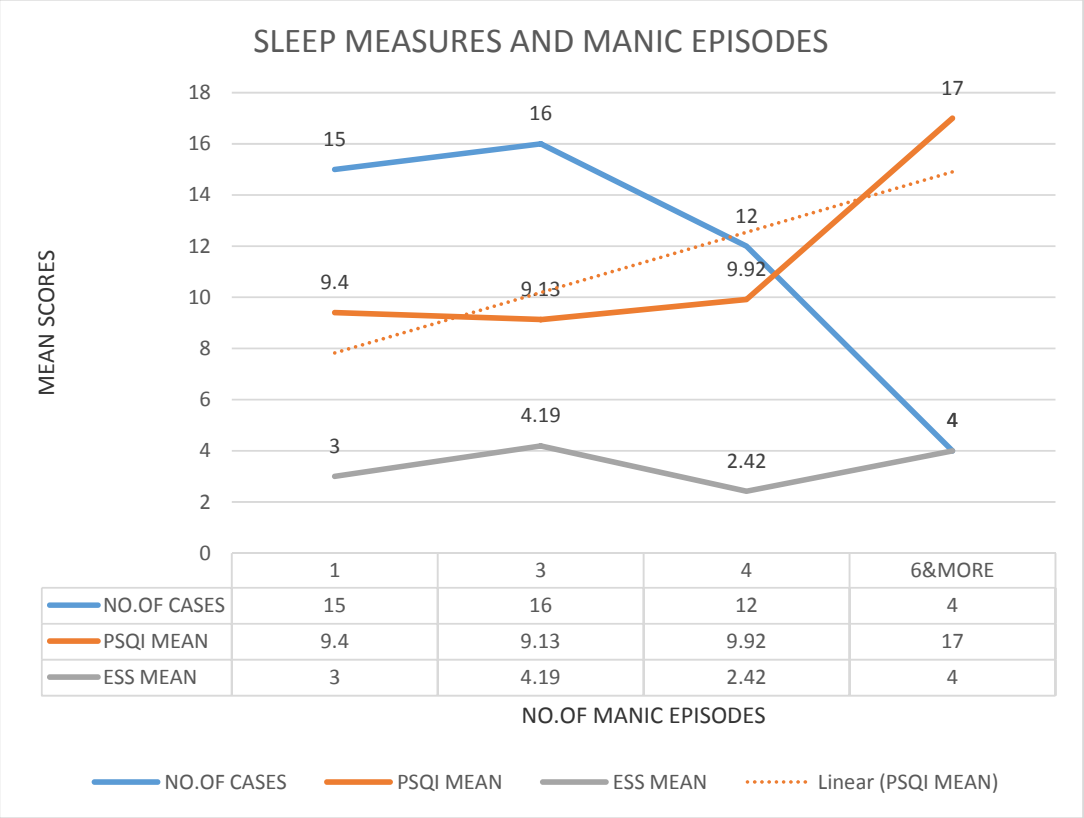
(TABLE 6.7) One way ANOVA to compare mean values between age at onset of illness (P VALUE < 0.05 IS SIGNIFICANT)

	Age at onset	**N**	**Mean**	**Std. Dev**	**F-Value**	**P-Value**
PSQI Global	11 - 20 years	22	8. 09	4. 396	2. 312	**0. 088**
	21 - 30 years	20	10. 70	4. 079		
	31 - 40 years	5	9. 20	1. 095		
	> 40 years	3	13. 00	. 000		
	Total	50	9. 54	4. 132		
Epworth Sleepiness Scale	11 - 20 years	22	3. 14	2. 100	5. 635	**0. 002**
	21 - 30 years	20	3. 65	2. 796		
	31 - 40 years	5	1. 20	1. 095		
	> 40 years	**3**	**8. 00**	**. 000**		
	Total	50	3. 44	2. 620		

We have divided the Age of onset of illness as in the above table. ie., 11-20years (N=22); 21-30years (N=20); 31-40years(N=5); >40 years(N=3).There is no differences between the age of onset of illness and sleep measures, particularly in PSQI (P0.08). But in ESS, patients more than 40 years has significant day time somnoloscence when compared to other age – group (p =0.002) (table 6.7)

One way ANOVA to compare mean values between number of manic episodes.

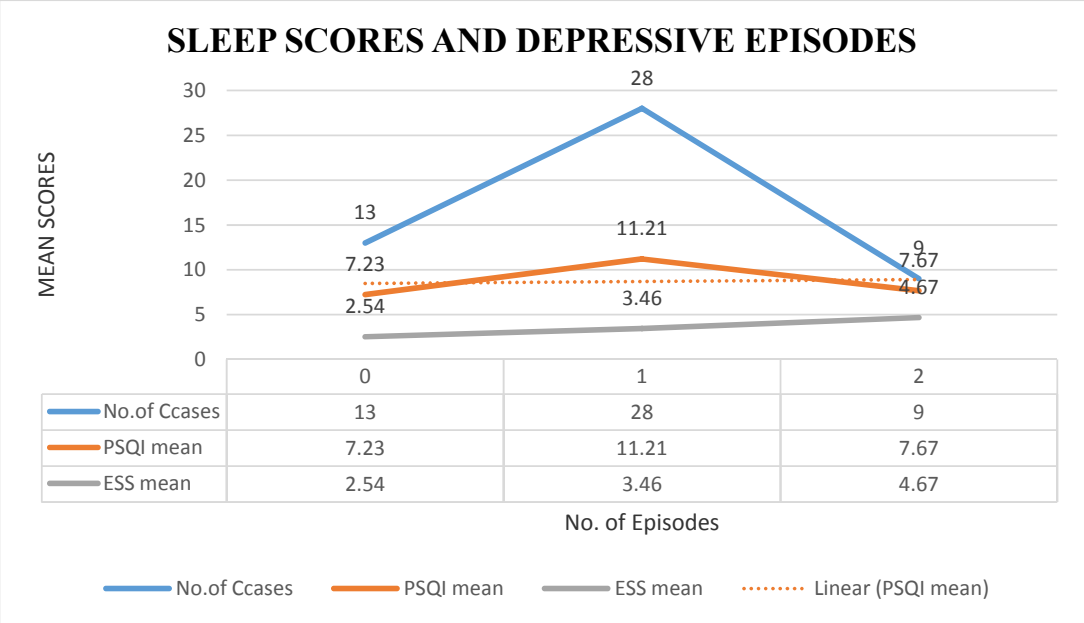
FIGURE 6.3



In the sample we have episodes of mania - one in no. in 15 cases, three in 16 cases, four in 12 cases, five in 3 cases and six or more episodes in 4 cases. When comparing no. of manic episodes and sleep scores, it is seen that as the number of manic episodes increases PSQI global mean scores increases from 9.40±2.230 for one single episode till 17.00±0.000 for 6 or more episodes (P<0. 001) and ESS scores also increases (figure 6.3). It concludes that there is direct relationship between manic episodes in a particular subject to the intensity of sleep

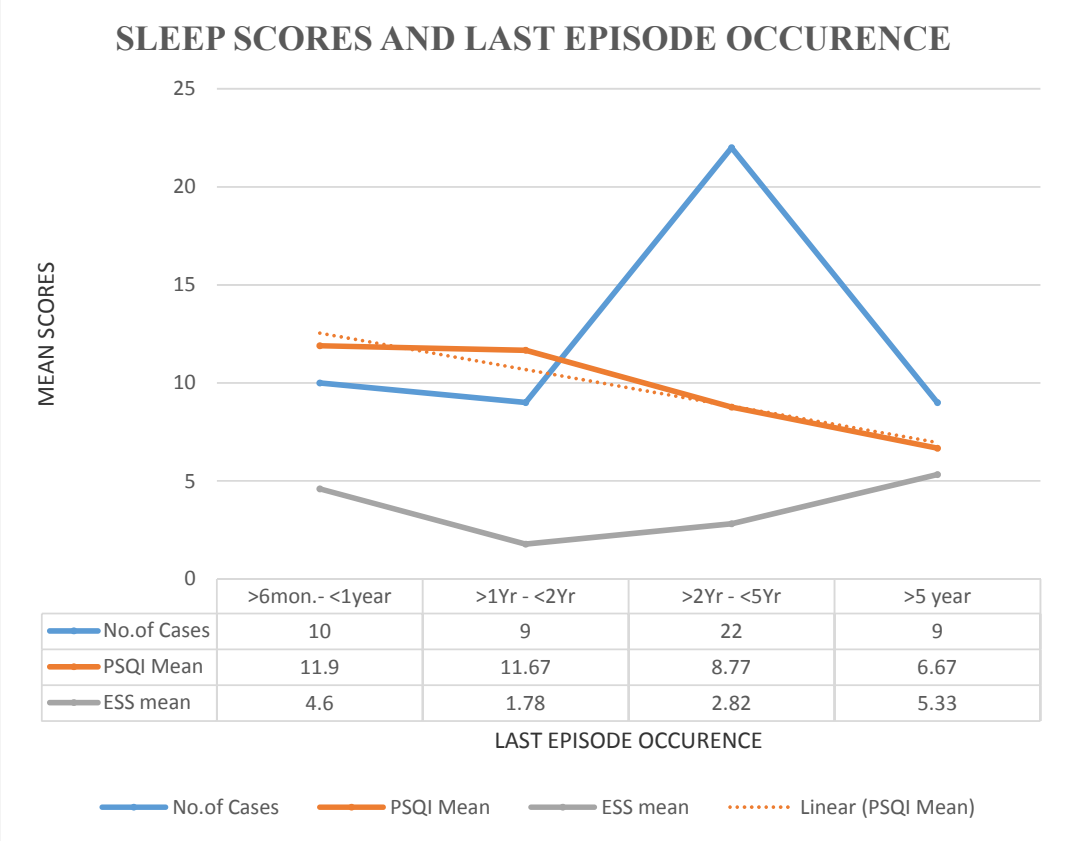
disturbances (poor sleep Quality) even in euthymic period, which in long run will lead to more relapses and recurrences, which in turn is one of the prodromal warning sign of recurrence of one more episode when the case is being followed up.

FIGURE 6.4 One way ANOVA to compare mean values between number of depressive episodes. (P VALUE < 0.05 IS SIGNIFICANT)



The number of depressive episodes is less when compared to manic episodes, this may be due to under reporting or under stated, Though it is we see a upward trend of poor sleep quality, particularly, patients complains of day time somnoloscence as seen in the linear plot of ESS score (p = 0. 174) though it is not that much significant when compared to PSQI scores. (P = 0. 003). (figure 6.4)

FIGURE 6.5 One way ANOVA to compare mean values between Sleep scores and Last episode occurences. (P VALUE < 0.05 IS SIGNIFICANT)



We have divided last episode occurrences into 1] 6 months earlier till 1 year before (N=10); 2] 1 year earlier till 2 years earlier (N=9) ; 3] 2 to 5 year earlier (N=22) and ; 4] more than 5 years earlier (N=9) .When the sleep quality and last episode occurrence are compared, it is seen that when the patients are in maintenance phase in long duration [Mean PSQI Global = 6.67±4.770], they tend to have less intensity of sleep disturbance (poor sleep Quality), when compared to recent occurences of

episodes [Mean PSQI Global = 11.90±4.408] ; (P = 0. 009). However all of them have poor sleep quality ie., all groups have mean score of Global PSQI more than 5. (Figure 6.5)

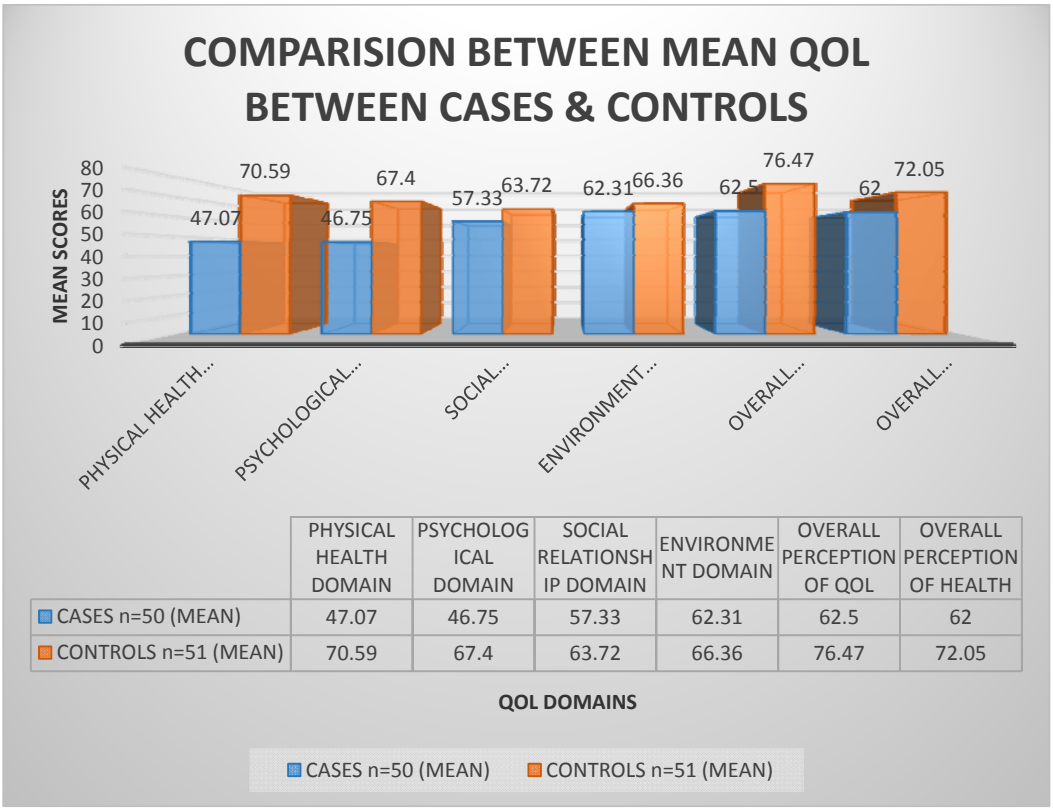
TABLE 6.8 Independent samples T-Test to compare mean values between suicides attempts. (P VALUE < 0.05 IS SIGNIFICANT)

Variable	Suicide attempts	N	Mean	Std. Dev	t-Value	P-Value
PSQI Global	Yes	9	9. 00	2. 291	0. 429	0. 670
	No	41	9. 66	4. 448		
Epworth Sleepiness Scale	Yes	9	3. 67	4. 093	0. 196	0. 849
	No	41	3. 39	2. 246		

In our study, it is seen that there is no relationship between sleep quality and suicide attempts. (Table 6.8)

QUALITY OF LIFE – WHOQOL-BREF

FIGURE 6.7 Independent sample T-Test to compare mean QOL between cases and controls (P VALUE < 0.05 IS SIGNIFICANT)



	PHYSICAL HEALTH DOMAIN	PSYCHOLOGICAL DOMAIN	SOCIAL RELATIONSHIP DOMAIN	ENVIRONMENT DOMAIN	OVERALL PERCEPTION OF QOL	OVERALL PERCEPTION OF HEALTH
CASES n=50 (MEAN)	47.07	46.75	57.33	62.31	62.5	62
CONTROLS n=51 (MEAN)	70.59	67.4	63.72	66.36	76.47	72.05

When compared to controls, euthymic BPAD cases have decrease in Quality of life in almost all the domains with 47.07± 8.7, 46.75±10.14, 57.33±12.09, 62.31±5.36, 62.50± 15.36, 62±18.38 when compared with 70.59±10.24, 67.40±8.56, 63.72±9.98, 66.36±9.71, 76.47±18.31, 72.05±19.13 in physical health domain, psychological health domain, social relationship domain, environmental domain, along with overall

perception of well being and health respectively, with P value of < 0. 05 as seen in above figure.6.7

TABLE 6.9 Correlations of QOL with Age

(P VALUE < 0.05 IS SIGNIFICANT)

QOL DOMAINS	Age	Cases	Controls
Physical health domain	**Correlation**	-. 064	**-. 332**
	P-Value	. 657	**. 017**
	N	50	51
Psychological domain	Correlation	-. 089	-. 079
	P-Value	. 539	. 584
	N	50	51
Social relationship domain	Correlation	-. 091	. 169
	P-Value	. 528	. 237
	N	50	51
Environment domain	Correlation	. 020	-. 276
	P-Value	. 891	. 050
	N	50	51
Overall perception of quality of life	Correlation	. 118	-. 312
	P-Value	. 414	. 026
	N	50	51
Overall perception of health	**Correlation**	**-. 286**	-. 011
	P-Value	**. 044**	. 940
	N	50	51

As the age advances the overall perception of Quality of health is decreased in patients (table 6.9), But in controls, as the age advances, there is decline in quality of physical health. This denotes that in

Euthymic bipolar patients though they are of any age they have similar decline in quality of life in all domains, only there perception of quality of health declines as age advances is significant, may be due to age factor.

TABLE 6.10 Independent samples T-Test to compare mean QOL between genders (CASES) (P VALUE < 0.05 IS SIGNIFICANT)

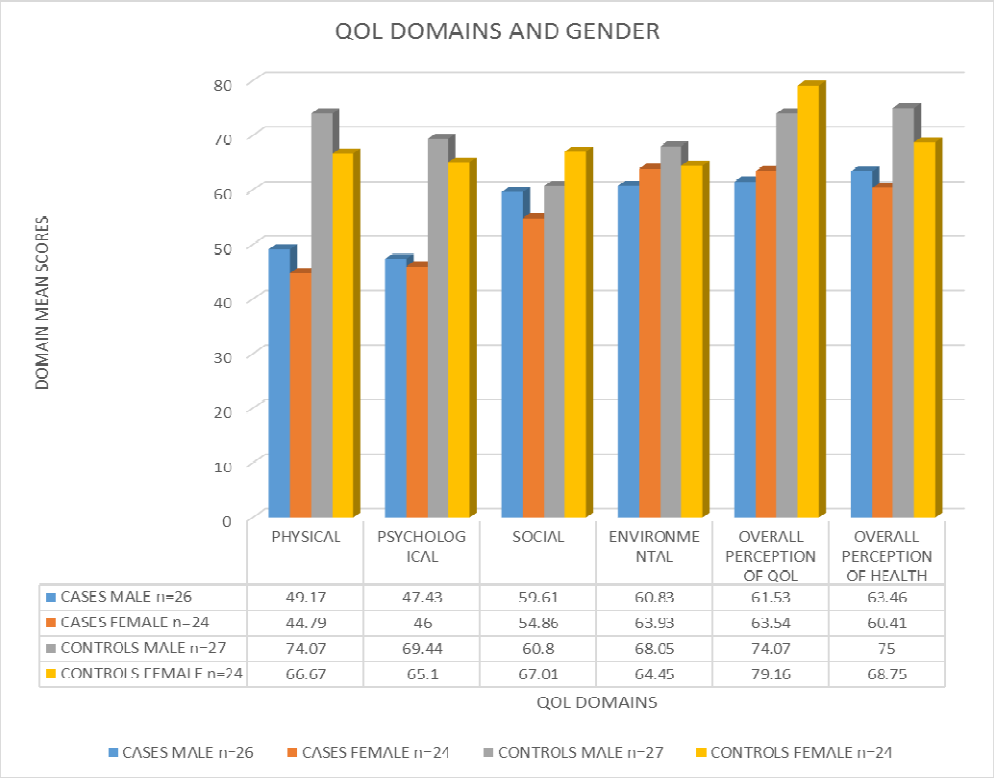
	Genders	N	Mean	Std. Dev	t-Value	P-Value
Physical health domain	Male	26	49. 1758	7. 58003	1. 820	0. 075
	Female	24	44. 7917	9. 41849		
Psychological domain	Male	26	47. 4359	12. 53201	0. 494	0. 624
	Female	24	46. 0069	6. 89369		
Social relationship domain	Male	26	59. 6154	14. 27747	1. 428	0. 161
	Female	24	54. 8611	8. 83172		
Environment domain	**Male**	**26**	**60. 8173**	**5. 74393**	**2. 136**	**0. 038**
	Female	**24**	**63. 9323**	**4. 41742**		
Overall perception of quality of life	Male	26	61. 5385	17. 65045	0. 457	0. 650
	Female	24	63. 5417	12. 72443		
Overall perception of health	Male	26	63. 4615	17. 65045	0. 581	0. 564
	Female	24	60. 4167	19. 38829		

TABLE 6.11 Independent samples T-Test (CONTROLS)

(P VALUE < 0.05 IS SIGNIFICANT)

QOL domains	Genders	N	Mean	Std. Dev	t-Value	P-Value
Physical health domain	Male	27	74. 0741	8. 83704	2. 741	**. 009**
	Female	24	66. 6667	10. 46112		
Psychological domain	Male	27	69. 4444	8. 72478	1. 849	**. 071**
	Female	24	65. 1042	7. 94498		
Social relationship domain	Male	27	60. 8025	7. 60075	2. 261	**. 029**
	Female	24	67. 0139	11. 38882		
Environment domain	Male	27	68. 0556	8. 59466	1. 332	. 189
	Female	24	64. 4531	10. 69957		
Overall perception of quality of life	Male	27	74. 0741	17. 65247	0. 991	. 326
	Female	24	79. 1667	19. 03467		
Overall perception of health	Male	27	75. 0000	16. 98416	1. 153	. 255
	Female	24	68. 7500	21. 17474		

FIGURE 6.8



When individual domains are compared according to gender in cases and controls, controls do better in all domains in both genders, particularly in physical and psychological domains. Females do better than males in Environmental domain (P value = 0. 038) in euthymic BPAD cases. (Table 6.10 and 6.11), (figure 6.8)

TABLE 6.12 Independent samples T-Test to compare mean QOL between marital statuses (CASES) (P VALUE < 0.05 IS SIGNIFICANT)

QOL Domain	Marital status	N	Mean	Std. Dev	t-Value	P-Value
Physical health domain	Single	13	47. 8022	4. 26046	0. 493	0. 625
	Married	37	46. 8147	9. 84517		
Psychological domain	**Single**	**13**	**52. 8846**	**3. 56188**	**4. 068**	**0. 001**
	Married	**37**	**44. 5946**	**10. 84156**		
Social relationship domain	**Single**	**13**	**63. 4615**	**9. 94107**	**2. 205**	**0. 032**
	Married	**37**	**55. 1802**	**12. 16390**		
Environment domain	Single	13	62. 7404	3. 24297	0. 333	0. 741
	Married	37	62. 1622	5. 92853		
Overall perception of quality of life	Single	13	63. 4615	12. 97186	0. 260	0. 796
	Married	37	62. 1622	16. 26775		
Overall perception of health	**Single**	**13**	**69. 2308**	**10. 96323**	**2. 191**	**0. 035**
	Married	**37**	**59. 4595**	**19. 85306**		

TABLE 6.13 Independent samples T-Test (CONTROLS)

(P VALUE < 0.05 IS SIGNIFICANT)

QOL domains	Marital status	N	Mean	Std. Dev	t-Value	P-Value
Physical health domain	**Single**	**5**	**79. 2857**	**11. 68245**	**2. 064**	**. 044**
	Married	**46**	**69. 6429**	**9. 75174**		
Psychological domain	Single	5	70. 8333	11. 41089	. 942	. 351
	Married	46	67. 0290	8. 27881		
Social relationship domain	Single	5	60. 0000	9. 12871	. 877	. 385
	Married	46	64. 1304	10. 07220		
Environment domain	Single	5	73. 7500	12. 99790	1. 833	. 073
	Married	46	65. 5571	9. 11656		
Overall perception of quality of life	Single	5	80. 0000	11. 18034	. 450	. 655
	Married	46	76. 0870	18. 97112		
Overall perception of health	Single	5	75. 0000	25. 00000	. 359	. 721
	Married	46	71. 7391	18. 71474		

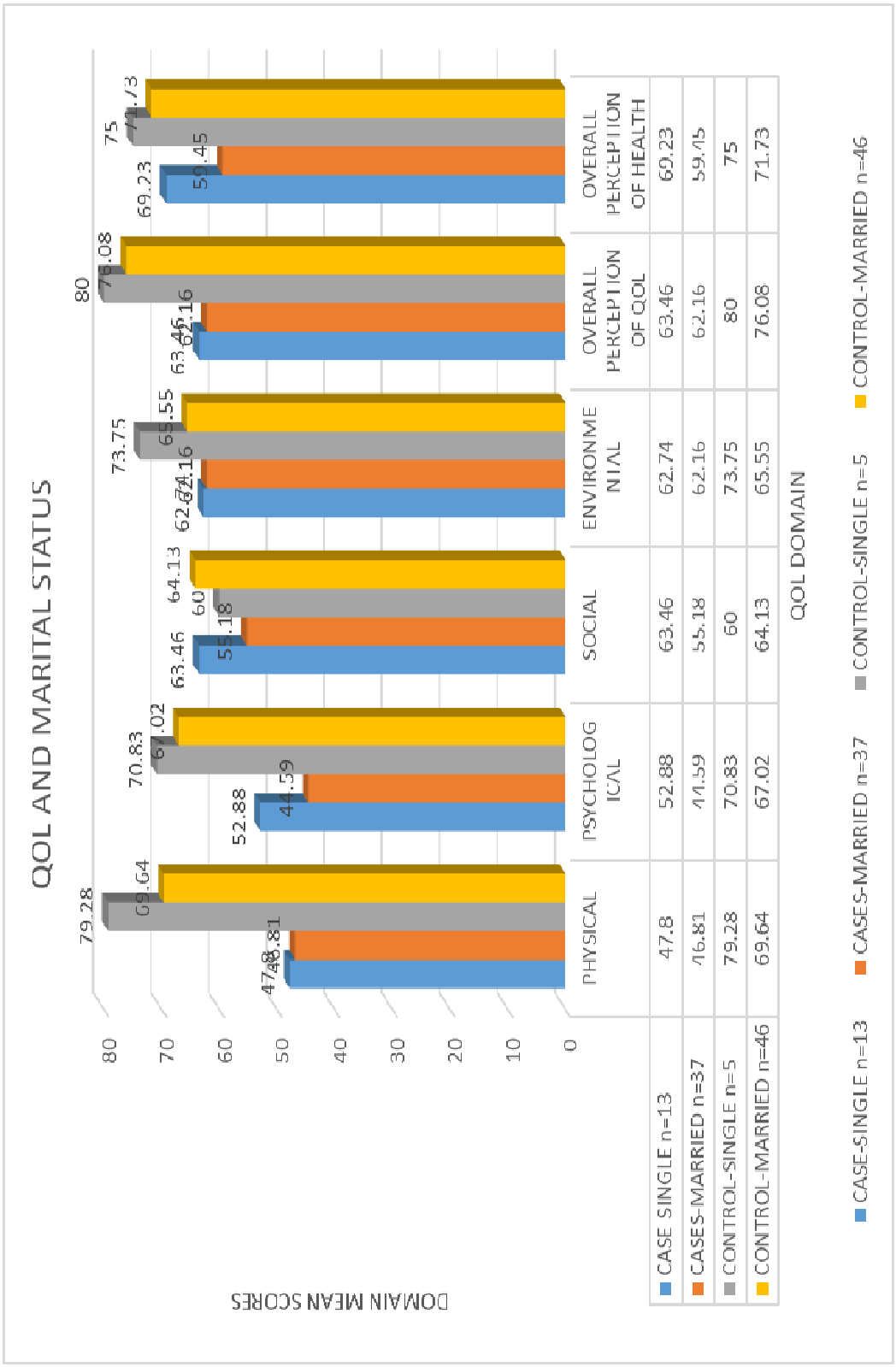

QOL AND MARITAL STATUS
DOMAIN MEAN SCORES
QOL DOMAIN
CASE-SINGLE n=13
CASES-MARRIED n=37
CONTROL-SINGLE n=5
CONTROL-MARRIED n=46
PHYSICAL
PSYCHOLOGICAL
SOCIAL
ENVIRONMENTAL
OVERALL PERCEPTION OF QOL
OVERALL PERCEPTION OF HEALTH
CASE SINGLE n=13 47.8 52.88 63.46 62.74 63.46 69.23
CASES-MARRIED n=37 46.81 44.59 55.18 62.16 62.16 59.45
CONTROL-SINGLE n=5 79.28 70.83 60 73.75 80 75
CONTROL-MARRIED n=46 69.64 67.02 64.13 65.55 76.08 71.73

FIGURE 6.9

When comparing marital status with QOL in Cases and controls, single person do well in almost all the domains and significant difference is seen in psychological domain, (P 0. 001) and social relationship domain (P = 0. 032), but in controls no significant difference in domains except in physical domain. (Table 6.12 and 6.13) (Figure 6.9)

TABLE 6.14 One way ANOVA to compare mean

QOL values between Socio economic status (CASES)

(P VALUE < 0.05 IS SIGNIFICANT)

QOL Domains	SES	N	Mean	Std. Dev	F-Value	P-Value
Physical health domain	Lower	5	47. 1429	11. 68245	. 461	. 633
	Upper Lower	38	46. 5226	9. 03839		
	Lower Middle	7	50. 0000	3. 57143		
	Total	50	47. 0714	8. 70911		
Psychological domain	Lower	5	48. 3333	4. 75073	2. 991	. 060
	Upper Lower	38	45. 0658	10. 47194		
	Lower Middle	7	54. 7619	7. 38671		
	Total	50	46. 7500	10. 14667		
Social relationship domain	**Lower**	**5**	**61. 6667**	**12. 63813**	**5. 386**	**. 008**
	Upper Lower	**38**	**54. 6053**	**11. 57580**		

	Lower Middle	**7**	**69. 0476**	**6. 29941**		
	Total	50	57. 3333	12. 09842		
Environment domain	Lower	5	62. 5000	3. 12500	1. 228	. 302
	Upper Lower	38	61. 7599	5. 74084		
	Lower Middle	7	65. 1786	3. 34077		
	Total	50	62. 3125	5. 33515		
Overall perception of quality of life	Lower	5	60. 0000	13. 69306	. 109	. 897
	Upper Lower	38	62. 5000	16. 18099		
	Lower Middle	7	64. 2857	13. 36306		
	Total	50	62. 5000	15. 36130		
Overall perception of health	Lower	5	65. 0000	13. 69306	. 153	. 859
	Upper Lower	38	61. 1842	19. 87917		
	Lower Middle	7	64. 2857	13. 36306		
	Total	50	62. 0000	18. 37811		

There is no significant difference except in social relationship domain, middle class do better in social relationship domain according to socioeconomic status, groups divided based on kuppusamy scale, which comprises Education, occupation and income derived by subjects. (Table

6.14) But there are no significant differences in controls as seen in below table.6.15

TABLE 6.15 One way ANOVA in Socio economic status (CONTROLS) (P VALUE < 0.05 IS SIGNIFICANT)

QOL domains	SES	N	Mean	Std. Dev	F-Value	P-Value
Physical health domain	Upper Lower	36	72. 0238	9. 29356	2. 476	. 122
	Lower Middle	15	67. 1429	11. 86046		
	Total	51	70. 5882	10. 24168		
Psychological domain	Upper Lower	36	67. 7083	8. 05333	. 154	. 697
	Lower Middle	15	66. 6667	9. 96024		
	Total	51	67. 4020	8. 56778		
Social relationship domain	Upper Lower	36	62. 7315	9. 65396	1. 221	. 275
	Lower Middle	15	66. 1111	10. 66567		
	Total	51	63. 7255	9. 97546		
Environment domain	Upper Lower	36	66. 1458	8. 82304	. 059	. 810
	Lower Middle	15	66. 8750	11. 91722		
	Total	51	66. 3603	9. 71444		

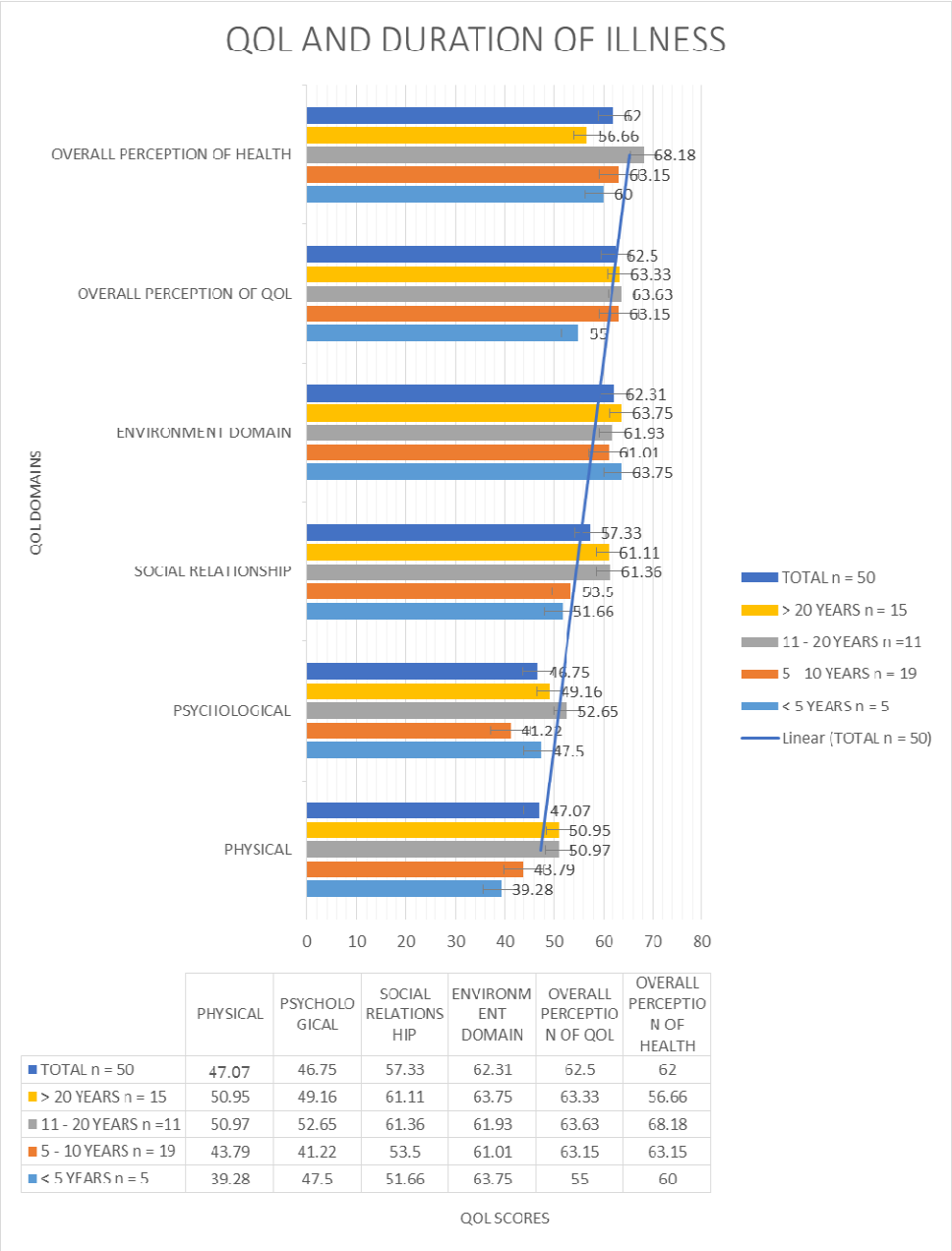
Overall perception of quality of life	Upper Lower	36	77. 0833	19. 24930	. 135	. 715
	Lower Middle	15	75. 0000	16. 36634		
	Total	51	76. 4706	18. 31104		
Overall perception of health	Upper Lower	36	72. 2222	19. 61939	. 009	. 926
	Lower Middle	15	71. 6667	18. 58058		
	Total	51	72. 0588	19. 13574		

TABLE 6.16 One way ANOVA to compare mean QOL values between Duration of illness) (P VALUE < 0.05 IS SIGNIFICANT)

QOL domains	Duration of illness	N	Mean	Std. Dev	F-Value	P-Value
Physical health domain	< 5 years	5	39. 2857	9. 78076	4. 901	**. 005**
	5 - 10 years	19	43. 7970	6. 82238		
	11 - 20 years	11	50. 9740	3. 60375		
	> 20 years	15	50. 9524	10. 23295		
	Total	50	47. 0714	8. 70911		
Psychological domain	< 5 years	5	47. 5000	3. 72678	4. 044	**. 012**
	5 - 10 years	19	41. 2281	12. 56885		
	11 - 20 years	11	52. 6515	9. 18043		
	> 20 years	15	49. 1667	4. 22577		
	Total	50	46. 7500	10. 14667		

Social relationship domain	< 5 years	5	51. 6667	3. 72678		
	5 - 10 years	19	53. 5088	13. 69751		
	11 - 20 years	11	61. 3636	12. 51262	2. 010	. 126
	> 20 years	15	61. 1111	9. 79283		
	Total	50	57. 3333	12. 09842		
Environment domain	< 5 years	5	63. 7500	4. 73930		
	5 - 10 years	19	61. 0197	7. 24452		
	11 - 20 years	11	61. 9318	2. 73082	. 867	. 465
	> 20 years	15	63. 7500	3. 88162		
	Total	50	62. 3125	5. 33515		
Overall perception of quality of life	< 5 years	5	55. 0000	11. 18034		
	5 - 10 years	19	63. 1579	19. 30821		
	11 - 20 years	11	63. 6364	13. 05582	. 428	. 734
	> 20 years	15	63. 3333	12. 90994		
	Total	50	62. 5000	15. 36130		
Overall perception of health	< 5 years	5	60. 0000	13. 69306		
	5 - 10 years	19	63. 1579	19. 30821		
	11 - 20 years	11	68. 1818	11. 67748	. 874	. 461
	> 20 years	15	56. 6667	22. 09288		
	Total	50	62. 0000	18. 37811		

FIGURE 6.10



	PHYSICAL	PSYCHOLOGICAL	SOCIAL RELATIONSHIP	ENVIRONMENT DOMAIN	OVERALL PERCEPTION OF QOL	OVERALL PERCEPTION OF HEALTH
TOTAL n = 50	47.07	46.75	57.33	62.31	62.5	62
> 20 YEARS n = 15	50.95	49.16	61.11	63.75	63.33	56.66
11 - 20 YEARS n =11	50.97	52.65	61.36	61.93	63.63	68.18
5 - 10 YEARS n = 19	43.79	41.22	53.5	61.01	63.15	63.15
< 5 YEARS n = 5	39.28	47.5	51.66	63.75	55	60

When we divide duration of illness as groups consisting of < 5years, 5-10 years, 11-20 years, , > 20 years we see that there is no uniform reduction in Quality of life according to duration of illness . When the duration of illness is less, patients have significant reduction in

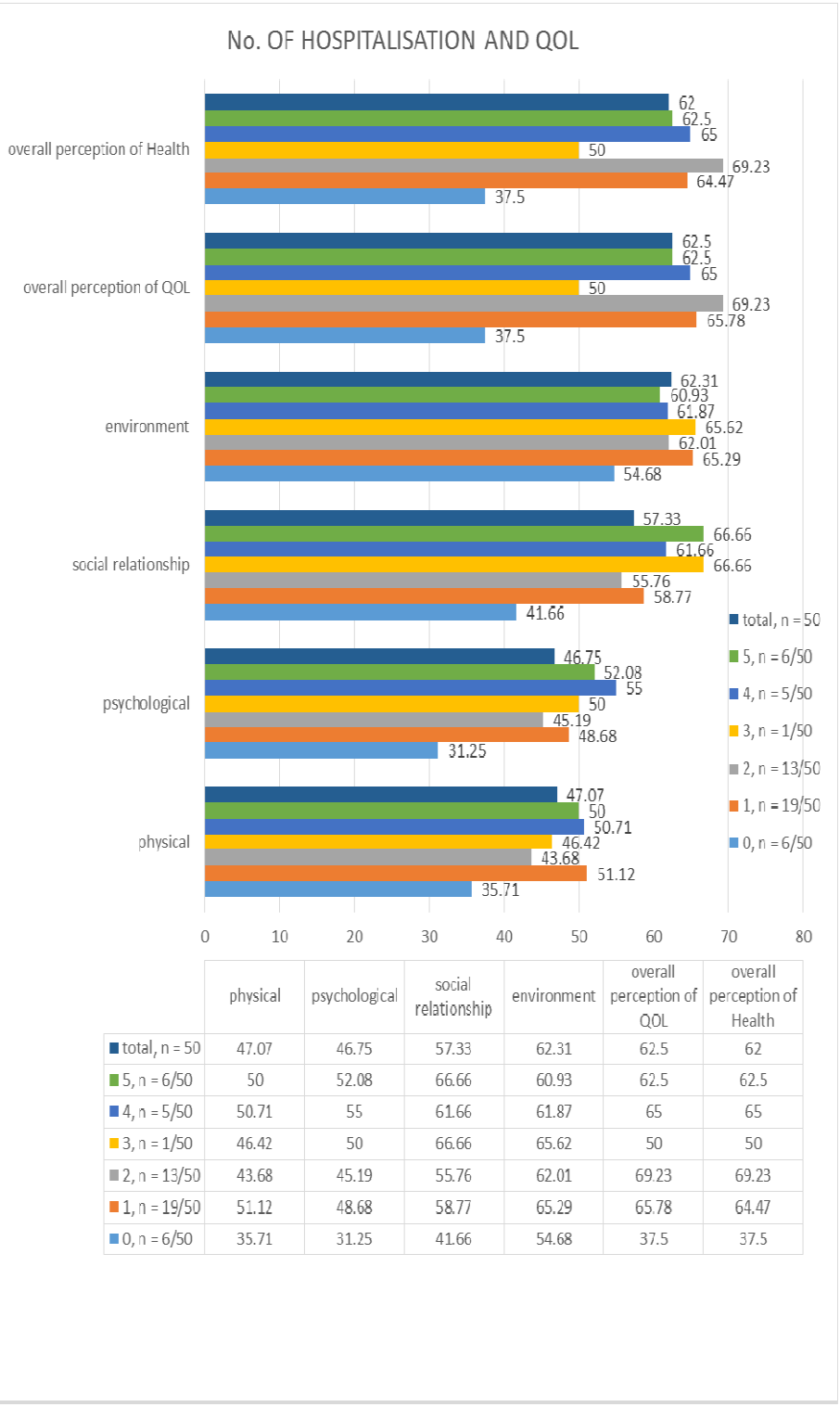
physical and psychological domain. And other domains are not significant. This may be due to, confounding factors of untreated illness, and drug compliance in between the episodes. And it needs to be cross checked with last episode occurrence. (Table 6.16) (figure6.10)

TABLE 6.17 One way ANOVA to compare mean QOL values between number of hospitalizations (P VALUE < 0.05 IS SIGNIFICANT)

QOL domains	Number of hospitali-sation	N	Mean	Std. Dev	F-Value	P-Value
Physical health domain	One	19	51. 1278	8. 91289	5. 044	**. 001**
	Two	13	43. 6813	7. 73633		
	Three	1	46. 4286	.		
	Four	5	50. 7143	3. 91230		
	Five	6	50. 0000	3. 91230		
	Nil	6	35. 7143	3. 91230		
	Total	50	47. 0714	8. 70911		
Psychological domain	One	19	48. 6842	5. 73539	6. 102	**. 001**
	Two	13	45. 1923	5. 60210		
	Three	1	50. 0000	.		
	Four	5	55. 0000	4. 56435		
	Five	6	52. 0833	11. 41089		
	Nil	6	31. 2500	15. 97524		
	Total	50	46. 7500	10. 14667		
Social	One	19	58. 7719	9. 81058	4. 016	**. 004**

relationship domain	Two	13	55. 7692	13. 77087		
	Three	1	66. 6667	.		
	Four	5	61. 6667	4. 56435		
	Five	6	66. 6667	9. 12871		
	Nil	6	41. 6667	9. 12871		
	Total	50	57. 3333	12. 09842		
Environment domain	One	19	65. 2961	4. 28158		
	Two	13	62. 0192	2. 80849		
	Three	1	65. 6250	.		
	Four	5	61. 8750	3. 42327	5. 600	**. 001**
	Five	6	60. 9375	1. 71163		
	Nil	6	54. 6875	8. 55816		
	Total	50	62. 3125	5. 33515		
Overall perception of quality of life	One	19	65. 7895	12. 38987		
	Two	13	69. 2308	10. 96323		
	Three	1	50. 0000	.		
	Four	5	65. 0000	13. 69306	6. 096	**. 001**
	Five	6	62. 5000	13. 69306		
	Nil	6	37. 5000	13. 69306		
	Total	50	62. 5000	15. 36130		
Overall perception of health	One	19	64. 4737	20. 94270		
	Two	13	69. 2308	10. 96323		
	Three	1	50. 0000	.		
	Four	5	65. 0000	13. 69306	3. 375	**. 011**
	Five	6	62. 5000	13. 69306		
	Nil	6	37. 5000	13. 69306		
	Total	50	62. 0000	18. 37811		

FIGURE 6.11



	physical	psychological	social relationship	environment	overall perception of QOL	overall perception of Health
total, n = 50	47.07	46.75	57.33	62.31	62.5	62
5, n = 6/50	50	52.08	66.66	60.93	62.5	62.5
4, n = 5/50	50.71	55	61.66	61.87	65	65
3, n = 1/50	46.42	50	66.66	65.62	50	50
2, n = 13/50	43.68	45.19	55.76	62.01	69.23	69.23
1, n = 19/50	51.12	48.68	58.77	65.29	65.78	64.47
0, n = 6/50	35.71	31.25	41.66	54.68	37.5	37.5

The quality of life actually shows increasing trend in all domains, as against the number of hospitalization, stating that, those who have relapses, and frequently visits hospitals, for their exacerbation, would have been stabilized in maintenance phase of the illness, as we have done only cross sectional analysis of the subjective quality of life for the previous month (table 6.17), (figure 6.11)

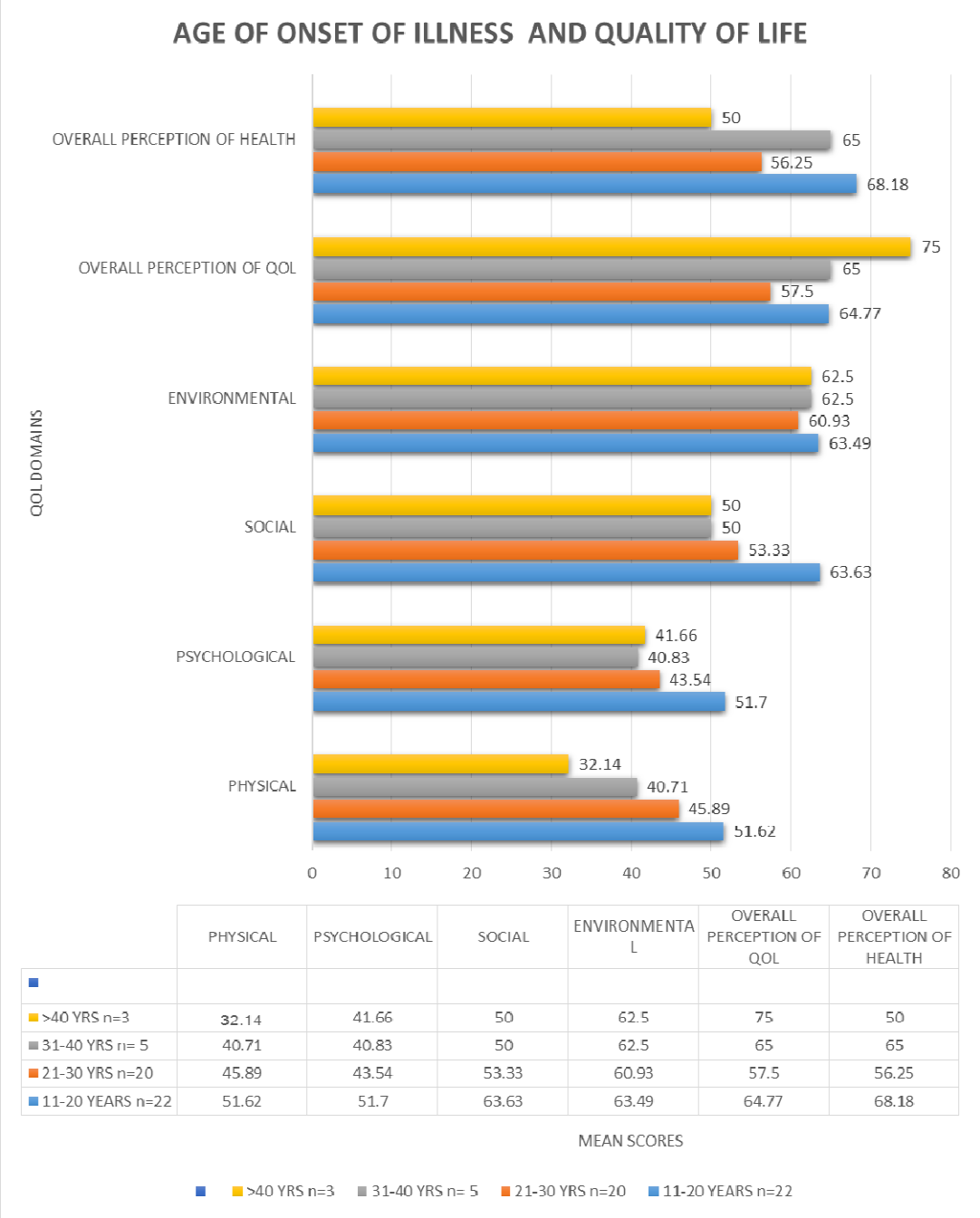
It has to be viewed in connection with the last episode occurrence, (figure 6.15)

TABLE 6.18 One way ANOVA to compare mean QOL values between Age of onset of illness: (P VALUE < 0.05 IS SIGNIFICANT)

QOL domains	Age of onset	N	Mean	Std. Dev	F-Value	P-Value
Physical health domain	11 - 20 years	22	51. 6234	6. 00931	8. 790	**. 001**
	21 - 30 years	20	45. 8929	8. 45750		
	31 - 40 years	5	40. 7143	7. 82461		
	> 40 years	3	32. 1429	. 00000		
	Total	50	47. 0714	8. 70911		
Psychological domain	11 - 20 years	22	51. 7045	6. 63922	3. 784	**. 017**
	21 - 30 years	20	43. 5417	12. 64355		
	31 - 40 years	5	40. 8333	4. 56435		
	> 40 years	3	41. 6667	. 00000		
	Total	50	46. 7500	10. 14667		

Social relationship domain	11 - 20 years	22	63. 6364	9. 10893	4. 489	**. 008**
	21 - 30 years	20	53. 3333	14. 15247		
	31 - 40 years	5	50. 0000	. 00000		
	> 40 years	3	50. 0000	. 00000		
	Total	50	57. 3333	12. 09842		
Environment domain	11 - 20 years	22	63. 4943	4. 35437	. 796	. 503
	21 - 30 years	20	60. 9375	6. 98771		
	31 - 40 years	5	62. 5000	. 00000		
	> 40 years	3	62. 5000	. 00000		
	Total	50	62. 3125	5. 33515		
Overall perception of quality of life	11 - 20 years	22	64. 7727	12. 58091	1. 634	. 194
	21 - 30 years	20	57. 5000	18. 31738		
	31 - 40 years	5	65. 0000	13. 69306		
	> 40 years	3	75. 0000	. 00000		
	Total	50	62. 5000	15. 36130		
Overall perception of health	11 - 20 years	22	68. 1818	11. 39606	2. 083	. 116
	21 - 30 years	20	56. 2500	24. 16364		
	31 - 40 years	5	65. 0000	13. 69306		
	> 40 years	3	50. 0000	. 00000		
	Total	50	62. 0000	18. 37811		

FIGURE 6.12



	PHYSICAL	PSYCHOLOGICAL	SOCIAL	ENVIRONMENTAL	OVERALL PERCEPTION OF QOL	OVERALL PERCEPTION OF HEALTH
>40 YRS n=3	32.14	41.66	50	62.5	75	50
31-40 YRS n= 5	40.71	40.83	50	62.5	65	65
21-30 YRS n=20	45.89	43.54	53.33	60.93	57.5	56.25
11-20 YEARS n=22	51.62	51.7	63.63	63.49	64.77	68.18

When we group the sample with the age of onset as 11 -20 years, 21 -30 years, 31 -40 years, and > 40 years, we find that, Age of onset of illness show a uniform trend in Quality of life in all four domains, stating

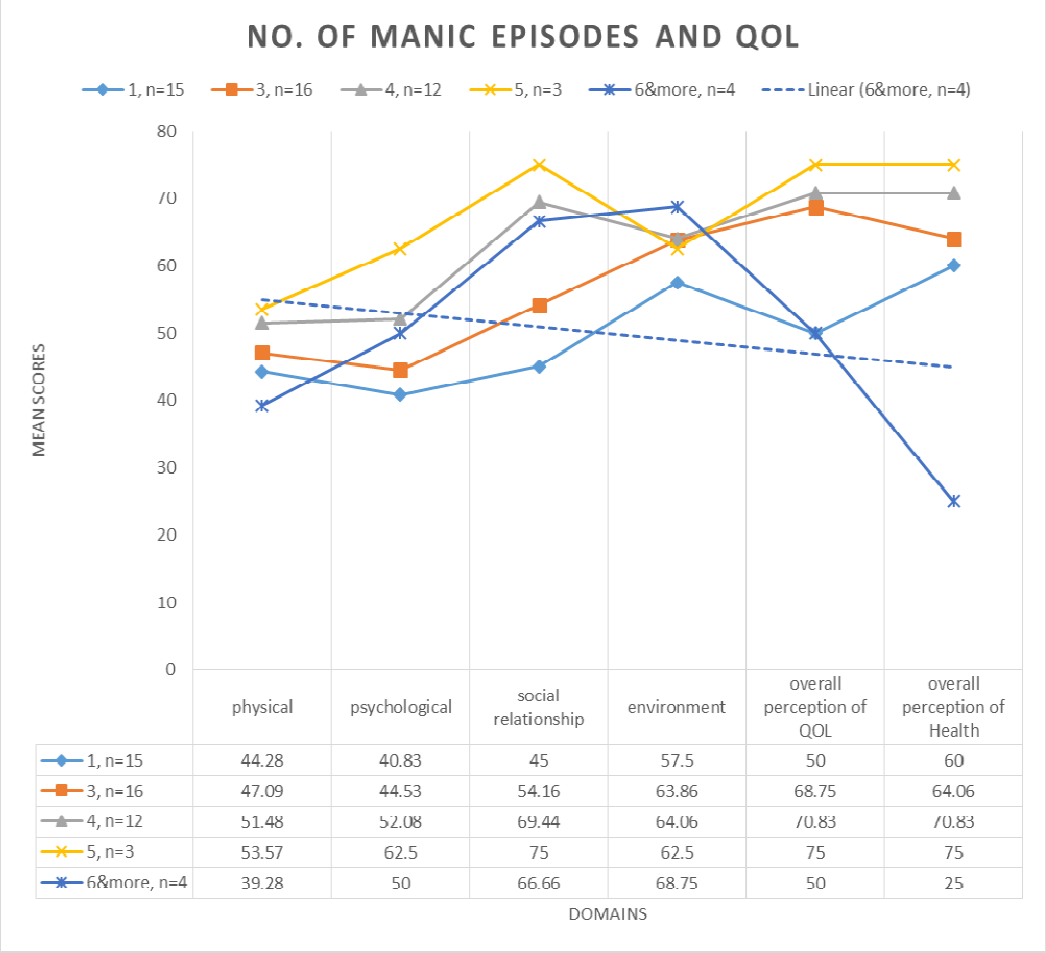
that higher the Age of onset, worse the Quality of life in physical, psychological, and social relationship domain with P value of 0. 001, 0. 017, 0. 008 respectively. (Table 6.18) (Figure 6.12)

TABLE 6.19 One way ANOVA to compare mean QOL values between No. of manic/mixed episodes (P VALUE < 0.05 IS SIGNIFICANT)

QOL domains	No of manic episodes	N	Mean	Std. Dev	F-Value	P-Value
Physical health domain	One	15	44. 2857	7. 96311	2. 702	**0. 042**
	Three	16	47. 0982	9. 14906		
	Four	12	51. 4881	8. 80872		
	Five	3	53. 5714	. 00000		
	Six or more	4	39. 2857	. 00000		
	Total	50	47. 0714	8. 70911		
Psychological domain	One	15	40. 8333	13. 74729	5. 880	**0. 001**
	Three	16	44. 5313	5. 83705		
	Four	12	52. 0833	3. 76889		
	Five	3	62. 5000	. 00000		
	Six or more	4	50. 0000	. 00000		
	Total	50	46. 7500	10. 14667		
Social relationship	One	15	45. 0000	6. 90066	36. 630	**<0. 001**
	Three	16	54. 1667	5. 27046		

domain	Four	12	69. 4444	7. 39688		
	Five	3	75. 0000	. 00000		
	Six or more	4	66. 6667	. 00000		
	Total	50	57. 3333	12. 09842		
Environment domain	One	15	57. 5000	5. 63986	8. 217	**<0. 001**
	Three	16	63. 8672	4. 26480		
	Four	12	64. 0625	2. 82667		
	Five	3	62. 5000	. 00000		
	Six or more	4	68. 7500	. 00000		
	Total	50	62. 3125	5. 33515		
Overall perception of quality of life	One	15	50. 0000	16. 36634	8. 262	**<0. 001**
	Three	16	68. 7500	11. 18034		
	Four	12	70. 8333	9. 73124		
	Five	3	75. 0000	. 00000		
	Six or more	4	50. 0000	. 00000		
	Total	50	62. 5000	15. 36130		
Overall perception of health	One	15	60. 0000	20. 70197	8. 343	**<0. 001**
	Three	16	64. 0625	12. 80869		
	Four	12	70. 8333	9. 73124		
	Five	3	75. 0000	. 00000		
	Six or more	4	25. 0000	. 00000		
	Total	50	62. 0000	18. 37811		

FIGURE 6.13



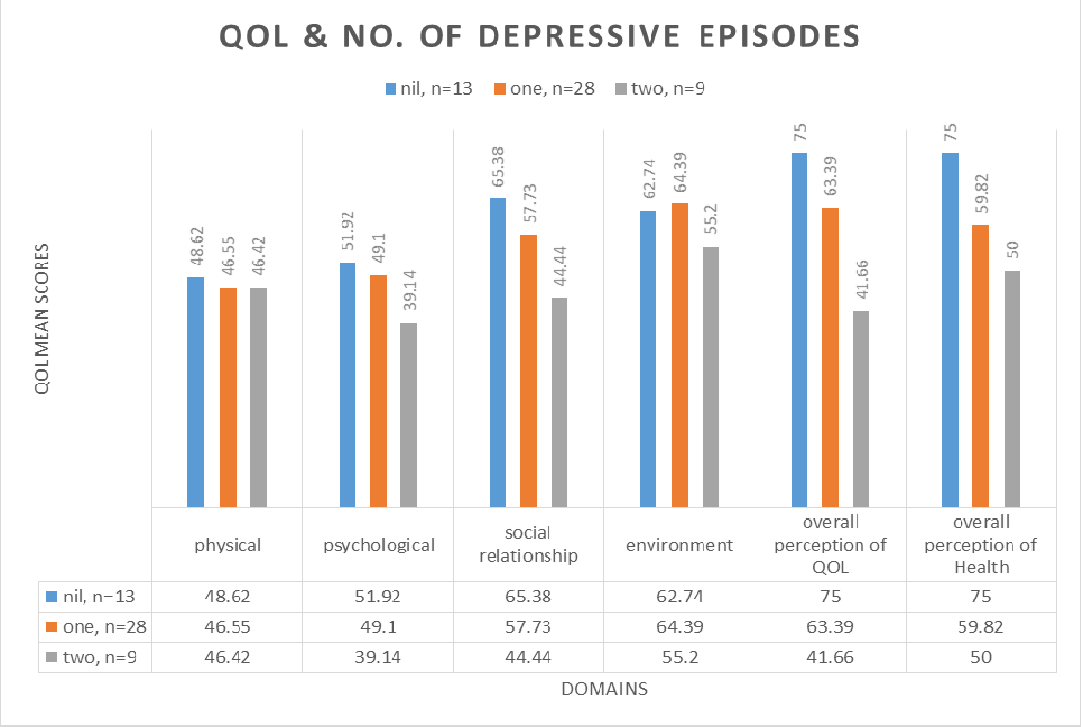
	physical	psychological	social relationship	environment	overall perception of QOL	overall perception of Health
1, n=15	44.28	40.83	45	57.5	50	60
3, n=16	47.09	44.53	54.16	63.86	68.75	64.06
4, n=12	51.48	52.08	69.44	64.06	70.83	70.83
5, n=3	53.57	62.5	75	62.5	75	75
6&more, n=4	39.28	50	66.66	68.75	50	25

As the number of manic episodes increases, the Quality of life is worsened as shown in linear plot, with significant reduction in all domains, more so in physical and psychological domain with P value of 0. 042 and 0. 001 respectively. (table 6.190, (figure 6.13)

TABLE 6.20 One way ANOVA to compare mean QOL values between No. of depressive episodes (P VALUE < 0.05 IS SIGNIFICANT)

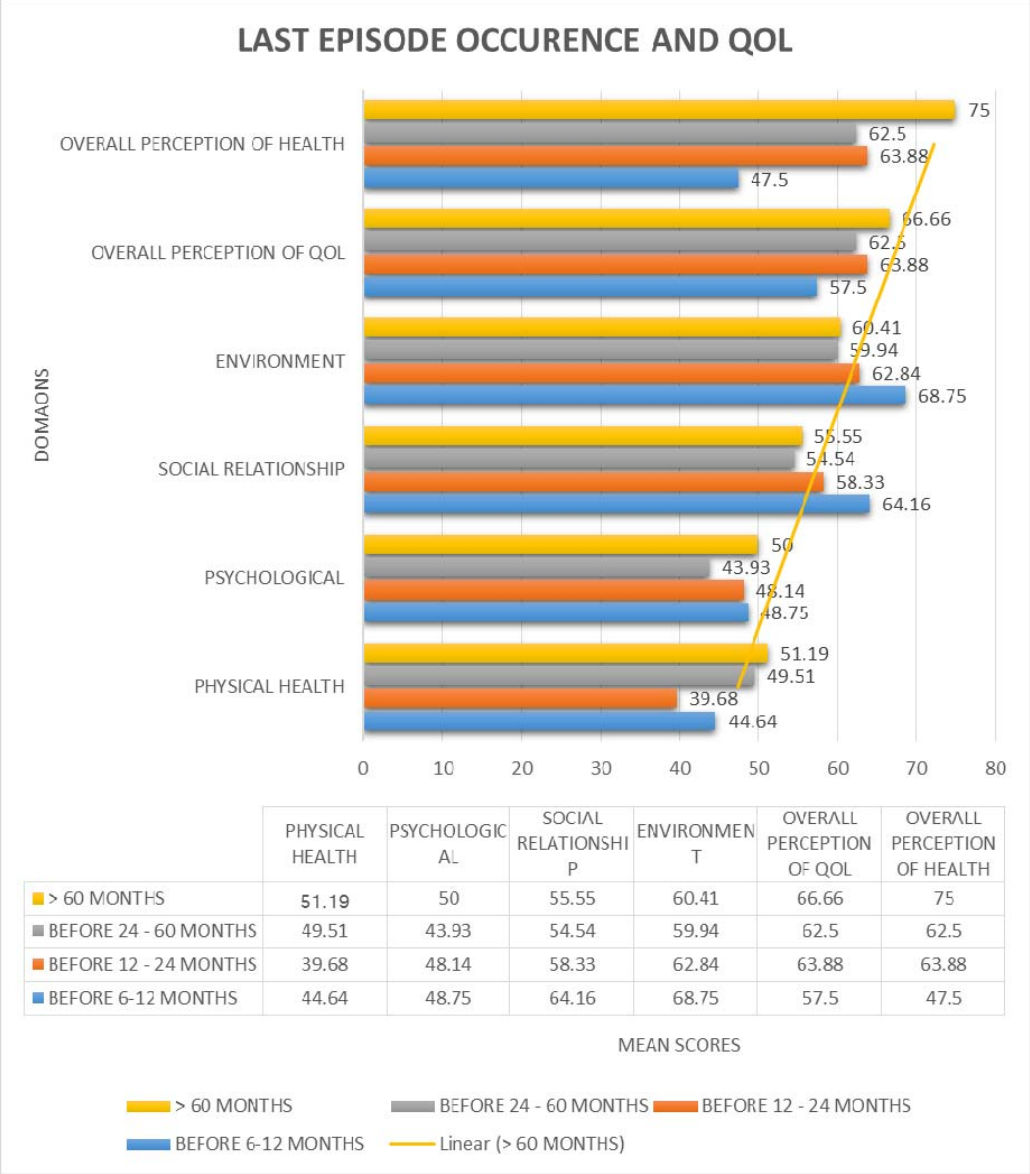
QOL domains	No of depressive episodes	N	Mean	Std. Dev	F-Value	P-Value
Physical health domain	One	28	46. 5561	10. 66931	. 272	. 763
	Two	9	46. 4286	6. 18590		
	Nil	13	48. 6264	4. 95268		
	Total	50	47. 0714	8. 70911		
Psychological domain	One	28	49. 1071	3. 82170	22. 657	**<0. 001**
	Two	9	31. 9444	11. 59951		
	Nil	13	51. 9231	9. 56450		
	Total	50	46. 7500	10. 14667		
Social relationship domain	One	28	57. 7381	9. 33173	11. 397	**<0. 001**
	Two	9	44. 4444	11. 02396		
	Nil	13	65. 3846	11. 20420		
	Total	50	57. 3333	12. 09842		
Environment domain	One	28	64. 3973	4. 01992	16. 646	**<0. 001**
	Two	9	55. 2083	6. 25000		
	Nil	13	62. 7404	2. 37361		
	Total	50	62. 3125	5. 33515		
Overall perception of quality of life	One	28	63. 3929	12. 69686	24. 998	**<0. 001**
	Two	9	41. 6667	12. 50000		
	Nil	13	75. 0000	. 00000		
	Total	50	62. 5000	15. 36130		
Overall perception of health	One	28	59. 8214	18. 43317	6. 593	**0. 003**
	Two	9	50. 0000	21. 65064		
	Nil	13	75. 0000	. 00000		
	Total	50	62. 0000	18. 37811		

FIGURE 6.14



As the number of depressive episodes increases, the Quality of life is worsened in all domains more so in psychological and social relationship domain with P value of < 0. 001 and < 0. 001 respectively, including overall perception of health and overall perception of Quality of Life. Though the physical health domain shows uniform reduction in comparison with other domains, it states that no. of episodes does not influence the physical health domain overall. (Table 6.20), (figure 6.14)

FIGURE 6.15

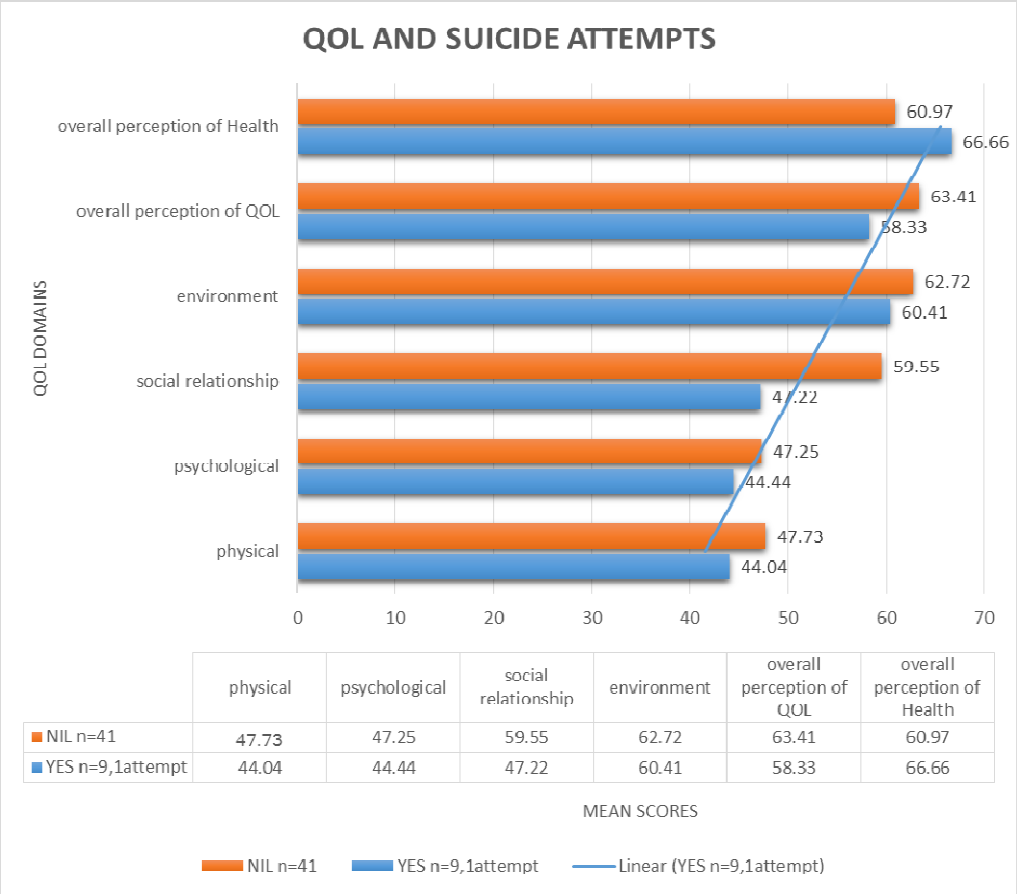


	PHYSICAL HEALTH	PSYCHOLOGICAL	SOCIAL RELATIONSHIP	ENVIRONMENT	OVERALL PERCEPTION OF QOL	OVERALL PERCEPTION OF HEALTH
> 60 MONTHS	51.19	50	55.55	60.41	66.66	75
BEFORE 24 - 60 MONTHS	49.51	43.93	54.54	59.94	62.5	62.5
BEFORE 12 - 24 MONTHS	39.68	48.14	58.33	62.84	63.88	63.88
BEFORE 6-12 MONTHS	44.64	48.75	64.16	68.75	57.5	47.5

We have grouped the sample as, last episode occurrence either manic or depressive, as before 6 to 12 months, before 12 – 24 months, before 24 – 60 months and > 60 months .While comparing last episode occurrence and various domains of QOL we see that after 60 months (5 years) of last episode all the domains have high scores, more

significant in physical health(P 0.008) and overall perception of health (P 0.009), but interestingly, stating as the stabilization period of Euthymic BPAD increases Quality of Life also improves. (figure 6.15)

FIGURE 6.16



As the suicide attempts prevail in samples we see that, they are severely affected in social relationship domain than nil suicide attempt in Euthymic BPAD cases having domain mean score of 59.55±12.15 and at least one suicide attempt history in Euthymic BPAD having 47.22±4.16 with P value of < 0. 001. (Figure 6.16)

TABLE 6.21 COMPARISION OF SLEEP AND QUALITY OF LIFE

Correlations between PSQI ESS and QOL

(P VALUE < 0.05 IS SIGNIFICANT)

QOL DOMAINS		PSQI Global	Epworth Sleepiness Scale
Physical health domain	**Correlation**	**-. 608**	**-. 370**
	P-Value	**<0. 001**	**<0. 001**
	N	101	101
Psychological domain	**Correlation**	**-. 539**	**-. 413**
	P-Value	**<0. 001**	**<0. 001**
	N	101	101
Social relationship domain	Correlation	-. 126	-. 220
	P-Value	. 210	. 027
	N	101	101
Environment domain	Correlation	-. 105	-. 299
	P-Value	. 294	. 002
	N	101	101
Overall perception of quality of life	**Correlation**	**-. 328**	**-. 285**
	P-Value	**. 001**	**. 004**
	N	101	101
Overall perception of health	**Correlation**	**-. 333**	**-. 197**
	P-Value	**. 001**	**. 048**
	N	101	101

While comparing Sleep and Quality of Life we see that when the patients have poor sleep quality the physical health domain and psychological domain is significantly affected with P value of < 0. 001 along with overall perception of quality of life and overall perception of health. (table 6.21)

TABLE 6.22Correlations between PSQI ESS and QOL among cases and controls(P VALUE < 0.05 IS SIGNIFICANT)

		Cases		Controls	
		PSQI Global	**Epworth Sleepiness Scale**	**PSQI Global**	**Epworth Sleepiness Scale**
Physical health domain	**Correlation**	**-. 330**	**. 115**	**-. 161**	**-. 260**
	P-Value	**. 019**	**. 426**	**. 260**	**. 066**
	N	50	50	51	51
Psychological domain	Correlation	-. 140	-. 166	-. 165	-. 114
	P-Value	. 333	. 250	. 246	. 425
	N	50	50	51	51
Social relationship domain	Correlation	. 157	-. 222	-. 169	. 079
	P-Value	. 275	. 121	. 237	. 583
	N	50	50	51	51
Environment domain	**Correlation**	**. 340**	**. 043**	**-. 219**	**-. 474**
	P-Value	**. 016**	**. 769**	**. 122**	**. 000**
	N	50	50	51	51
Overall perception of quality of life	Correlation	-. 052	. 051	-. 289	-. 386
	P-Value	. 719	. 727	. 040	. 005
	N	50	50	51	51
Overall perception of health	**Correlation**	**-. 316**	**-. 059**	**-. 088**	**-. 152**
	P-Value	**. 026**	**. 684**	**. 540**	**. 287**
	N	50	50	51	51

But when compared once again with controls physical health domain is only significantly affected when the Euthymic BPAD subjects have poor sleep quality with p value of 0. 019. Interestingly Overall perception of health is decreased in euthymic BPAD subjects with sleep disturbance than controls with P value of 0. 026 (table 6.22)

COMPARISION OF SLEEP HYGEINE:

TABLE 6.23 Chi-Square test to compare the proportions between cases and controls (P VALUE < 0.05 IS SIGNIFICANT)

SLEEP HYGEINE		Cases		Controls		P - VALUE
		N	%	N	%	
Quiet bedroom	Yes	50	100. 0	48	94. 1	0. 243
	No	0	. 0	3	5. 9	
Mattress comfortable	Yes	50	100. 0	51	100. 0	-
	No	0	. 0	0	. 0	
Alcohol as a sleep aid	Yes	0	. 0	0	. 0	-
	No	50	100. 0	51	100. 0	
Exercise within 4 hrs of going to bed	Yes	3	6. 0	3	5. 9	0. 999
	No	47	94. 0	48	94. 1	
Reading while in bed	**Yes**	**0**	**. 0**	**9**	**17. 6**	**0. 003**
	No	50	100. 0	42	82. 4	
Watching television while in bed	**Yes**	**27**	**54. 0**	**15**	**29. 4**	**0. 021**
	No	23	46. 0	36	70. 6	
Using telephone	Yes	12	24. 0	12	23. 5	0. 999

while in bed	No	38	76. 0	39	76. 5	
Playing radio while in bed	Yes	15	30. 0	15	29. 4	0. 999
	No	35	70. 0	36	70. 6	
Desk with paper work in bedroom	**Yes**	**0**	**. 0**	**9**	**17. 6**	**0. 003**
	No	50	100. 0	42	82. 4	
Tea / coffee / caffeinated soft drinks after 5 pm	Yes	25	50. 0	24	47. 1	0. 923
	No	25	50. 0	27	52. 9	
Cigarettes after 5 pm	**Yes**	**6**	**12. 0**	**0**	**. 0**	**0. 013**
	No	44	88. 0	51	100. 0	
Standard cups of tea/ day	< 2 times	6	12. 0	0	. 0	**<0. 001**
	2 - 4 times	**9**	**18. 0**	**33**	**64. 7**	
	> 4 times	4	8. 0	0	. 0	
	0 time	31	62. 0	18	35. 3	
Standard cups of coffee / day	< 2 times	6	12. 0	3	5. 9	**<0. 001**
	2 - 4 times	**25**	**50. 0**	**9**	**17. 6**	
	> 4 times	0	. 0	0	. 0	
	0 time	19	38. 0	39	76. 5	
Standard cups of coffeinated drinks / day	0 time	50	100. 0	51	100. 0	-
Number of cigarettes /day	**> 4 times**	**7**	**14. 0**	**1**	**2. 0**	**0. 031**
	0 time	43	86. 0	50	98. 0	

While comparing the sleep hygiene in cases and controls, which may be a confounding factor, we noticed that cases watch television while in bed, more number of euthymic BPAD subjects have coffee and cigarettes more times than the controls. And controls read while in bed and do some paper work and more number of controls take tea than BPAD subjects, which may be a reason for significant sleep disturbance in the percentage observed. (table 6.23)

DISCUSSION

The present study shows similar results in accordance to the previous studies. But in addition we have taken into account Sleep Hygiene pertaining to the individuals and how it interferes with the Sleep Quality overall. Also compared the Quality of life with Quality of sleep measures in Bipolar Affective disorder subjects.

First, we ensured our sample is age and sex matched. In socio-demographic profile we see that in marital status, some of the patients were unmarried, unemployed, and mostly of lower class in kuppusamy modified socioeconomic scale. This may be due to the direct influence of the illness affecting their sociodemographic status. Second, all cases were in maintenance phase of treatment, and were in euthymic phase as per the HDRS and YMRS scale stating that they are in remission or in recovery phase.

QUALITY OF SLEEP

When we compared with controls in sleep measures, 88 % of cases had poor sleep quality or sleep disturbances, even in their remission phase of their illness, as against the healthy controls who were only 51 %. This is in accordance with the study by Paul Brocha et al., [113] with regards to Euthymic BPAD which shows 82.9% of the sample had poor sleep

quality, but the poor sleep quality in controls is high in our sample against 21.2% in the study conducted by Paul Brocha et al.,

Our study replicate and extend the previous studies findings by Paul Brocha et al., and Walz et al.[114, 115] with regards to subcomponents. Euthymic BD patients have decreased subjective sleep quality, sleep latency is increased, and sleep duration is decreased and have decreased habitual sleep efficiency. Day time dysfunctions were more in BPAD samples and most of them need support of medications to maintain their sleep. And overall disturbance in sleep intensity is very high when compared to cases.

We report significant new findings in terms of Quality of sleep compared with various clinical variables of Bipolar affective disorder subjects under remission, They are as follows,

When comparing the clinical variables of the illness, we see that, sleep disturbances prevails over the entire period and intensity is more during 5 -10 years of illness and > 20 years of illness, where there is chances of more relapses and subsyndromal sleep disturbances. Interestingly we noted that though they have sleep disturbance, there was no significant relationship between age of onset of illness and sleep disturbances but when the age of onset of illness more than 40 years of age have significant day time somnolescence.

When comparing no. of manic episodes occurrences and sleep disturbances, we see direct relationship. As the no. of episodes increases, the intensity of sleep disturbance increases even in euthymic period with high PSQI scores, which in long run will lead to more relapses and recurrences .sleep disturbances as such which occurs 2 weeks prior to the episodes, as discussed earlier, will be a prodromal warning sign for any manic episodes to follow, within a short duration. And these patients should be carefully monitored and caregiver should be alerted of the important warning sign of impending episode, i.e., just monitoring their sleep pattern and quality.

In our sample size, the number of depressive episodes is less, as this might be understated or overlooked. Anyhow, they show a significant sleep disturbance intensity when the number of episodes increases.

Interestingly when we compare with last episode occurrence, we notice inverse relationship. When the patients gets stabilized for a long period of time in an increasing trend, the sleep quality also increases as against with recent occurrences, which will have significant intensity of sleep disturbances. Also quality of life improves when the euthymic period gets stabilized for a long period of time, Approximately 5 years than compared to subjects with last episode occurrence within 5 years.

When comparing Quality of life of Euthymic BPAD subjects with healthy controls, Euthymic BD patients have significant reduction in all domains of quality of life.

QUALITY OF LIFE:

In Bipolar affective disorder subjects even though they achieve symptomatic remission, they are associated with functional deficits. Our study is in accordance with the previous studies in term of Quality of Life as seen in Depp c et al.,[116] In all domains the Quality of life was affected when compared to healthy controls, This in accordance with the study conducted by Sierra et al., but the scales used was different, there Sf-16 was used[117], but we used WHO-QOL-Bref.

As the age advances, the overall perception of quality of life is decreased in patients. But in controls as the age advances, there is decline in quality of life in physical health domain, which denotes that in Euthymic BD patients though they are of any age, they have similar decline in Quality of life in all domains and only the perception of quality of life is declining in healthy controls, may be a age related factors.

When comparing individual domain according to gender in cases and controls, controls do better in all domains, especially in physical and psychological domain. Females do better in Environmental domain in patients.

And regarding marital status, singles do better than married persons, particularly in psychological and social relationship domain .And we see there is no significant differences according to classes divided by kuppusamy socioeconomic scale based on employment status and income in any of the domains. But as usual controls do well in all the domains of quality of life when compared to cases.

When comparing clinical variables of the Euthymic BPAD patients and Quality of life domains, we see that Duration of illness has conflicting results, showing that when the duration of illness is less, patients have significant reduction in physical and psychological domains. But which in turn shows that the bipolar patients' takes years to stabilize with their euthymic phase to regain back their quality of life.

Also interestingly, we see that QOL actually shows a increasing trend (good quality) in all domains as against the no. of hospitalization i.e., inversely related, stating that, those who have relapses and frequently visits hospitals for their exacerbation, would have been stabilized in their maintenance phase of illness, as we have dine only cross sectional analysis of the subjective Quality of life for the previous month. It has to be viewed in continuous with last episode occurrence.

When comparing Age of onset of illness with QOL, it shows a uniform trend, i.e., directly proportional, as the age of onset of illness

increases, QOL in physical, psychological and social relationship quality decreases.

When the number of episodes increases,both in manic and depressive episodes viewed separately or together, worsens the Quality of life in all domains. When comparing last episode occurrence and QOL, we come to the conclusion that as the stabilization of Euthymic BPAD increases more than 5 years, Quality of Life improves significantly.

Interestingly, we notice that, the euthymic BPAD patients with the suicide attempts have significant reduction in QOL in particular domain, which is social relationship domain, which would be a factor for perceived loneliness and their negative perception about the interpersonal relationship with the family members and the society.

When comparing sleep and QOL, we see that physical health and psychological domain is affected along with overall perception of quality of life and health. When Euthymic BD subjects have sleep disturbances, cross checked with controls, it emphasizes that overall perception of health and physical health domain is significantly affected than psychological domain.

CONCLUSIONS

Thus we see that Bipolar affective disorder patients though they are in remission have

1] Significant sleep disturbance in means of sleep onset, duration and sleep efficiency and also have severe daytime dysfunctions.

2] Sleep hygiene should also be taken care of, as they are easily modifiable factors

3] As the duration of illness increases sleep disturbance also get marked when compared to duration of illness less than 20 years.

4] When the Age of onset of illness is 40 years and above, they have significant daytime somnolescence even if they are in remission.

5] As the last episode occurrence gets far from the period of observation sleep quality and QOL also improves significantly.

6] No. of episodes are directly related to sleep disturbances, more so in mania than in depression.

7] Duration of illness is inversely related to all domains of quality of life.

8] Age of onset of illness is inversely related to Quality of Life domains, ie., it worsens as the age of onset increases.

9] No. of episodes is directly related to the Quality of life, as the No. of episodes increases in both mania and depressive episode QOL decreases in its scores.

10] In patients who had undergone suicide attempt, social relationship domain is significantly affected than other domains of QOL.

CLINICAL IMPLICATIONS:

The present study has several important clinical implications. Treating subjects with poor sleep quality in periods of symptomatic remission, is a challenging tasks, and targets to improve the sleep quality along with mood symptoms would improve the BPAD outcome. Clinicians should be vigilant in treating the Subjective sleep disturbances by various methods, starting from better sleep hygiene factors to CBT-I (cognitive Behavior therapy in insomnia) like sleep restriction therapy, stimulus control therapy and relaxation training to judicious use of medications, targeting the particular area of affected sleep quality. With regards to QOL, we need better psychosocial intervention to address the patients need to achieve a better Quality of life.

STRENGTH OF THE STUDY:

The sample is taken from a tertiary care hospital with good maintenance of Hospital records with Quantifying the severity of illness with widely used scales in longitudinal follow up of the patients. Second, the sample is Age and sex matched.And various clinical variables which would influence the outcome, ie., sleep and quality of life is studied extensively with good statistical significances. We used all scales which shows good test-retest and interrater reliability. We have used an internationally accepted scale for QOL particularly, with the local language of the participants.

LIMITATION OF THE STUDY:

1] It is a cross –sectional design rather than a longitudinal follow up study.

2] There are more chances of recall bias in participants, as they might recall the previous two to three days of sleep quality, even though the scale is meant to assess subjectively the sleep quality in previous month.

3] In case of QOL, the subjects have more chance of answering in pertain to their prevailing mood and perception at that point of time, Moreover we have used only one scale to observe a broad topic of Quality of life.

5] Since it is conducted in Tertiary care hospital, the results obtained could not be generalized to community setting.

6] Use of subjective measures like PSQI rather than an Objective measures like Polysomnography, which would be more accurate while comparing with Subjective sleep Quality.

FUTURE DIRECTIONS

The findings of our present study, shows, Bipolar affective disorder subjects have sleep disturbances outside of acute episodes, even if they classify for symptomatic remission. And in current scenario, there is wide need of interventions in sleep-wake disturbances in inter-episode Bipolar Affective disorder. And in near future there is possibility of finding candidate endophenotype for Bipolar affective disorder, which will provide foundation to improve sleep-wake disturbance in Euthymic Bipolar affective disorder. And we need a comprehensive approach to cater, possibly including psychosocial interventions to address the improvement of various domains of Quality of Life, leading to important goal of achieving adequate functional recovery in Bipolar Affective Disorder subjects.

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ANNEXURE

PATIENT INFORMATION SHEET

TITLE : A Study on Bipolar Affective Disorder Subjects Under remission – Quality of Sleep and Quality of Life.

Principal Investigator:

Participants Name:_____

Place of Study : Institute of Mental health ,Chennai

Purpose of Study :

To study about the extent of Sleep disturbance and Quality of life in subjects of Bipolar Affective disorder in remission.

The purpose of the study is to compare the sleep and Quality of life of Euthymic Bipolar Affective Disorder subjects with Healthy controls.

To assess this ,questionnaires' are used to score your Quality of sleep and Quality of Life. They are

1] Pittsburgh Sleep Quality Index

2] Epworth Sleepiness Scale

3] WHOQOL – Bref

By participating in this study you wont be harmed in any purpose .There won't be any intervention in your current treatment.

I assure you that medicines are not used to test in you.During the publication of result or conclusion of the study or during the study ,your name or identity will not be disclosed.

The result of the study will be shared with you during the course of the study and during the end of the study.

It is of your own interest you can participate in the study and at any time you can leave the study.

Signature :

(Principal Investigator) Participants Signature/

Left thumb impression

Witness :

INFORMED CONSENT FORM

Title of the study - **"A STUDY ON BIPOLAR AFFECTIVE DISORDER SUBJECTS UNDER REMISSION – QUALITY OF SLEEP AND QUALITY OF LIFE"**
Name of the participant: _____

Name of the Principal/Co-Investigator:

Name of the Institution: MADRAS MEDICAL COLLEGE, CHENNAI

Name and address of the sponsor / agency (ie), if any:

I, _____, have read the information in this form (or it has been read to me). I was free to ask any questions and they have been answered. I am over 18 years of age and, exercising my free power of choice, hereby give my consent to be included as a participant in the study **titled "A STUDY ON BIPOLAR AFFECTIVE DISORDER SUBJECTS UNDER REMISSION – QUALITY OF SLEEP AND QUALITY OF LIFE"**

(1) I have read and understood this consent form and the information provided to me.

(2) I have had the consent document explained to me.

(3) I have been explained about the nature of the study.

(4) I have been explained about my rights and responsibilities by the investigator.

(5) I have informed the investigator of all the treatments I am taking or have taken in the past months/ years including any native (alternative) treatments.

(6) I have been advised about the risks associated with my participation in the study.✶

(7) I agree to cooperate with the investigator and I will inform him/her immediately if I suffer unusual symptoms.✶

(8) I have not participated in any research study within the past _____ month(s).✶

(9) [I have not donated blood within the past _____months -- Add if the study involves extensive blood sampling]✶

(10) I am aware of the fact that I can opt out of the study at any time without having to give any reason and this will not affect my future treatment in the hospital.✶

(11) I am also aware that the investigators may terminate my participation in the study at any time, for any reason, without my consent.✶

(12) I hereby give permission to the investigators to release the information obtained from me as result of participation in this study to the sponsors, regulatory authorities, Government agencies, and ethics committee. I understand that they may inspect my original records.

(13) I understand that my identity will be kept confidential if my data are publicly presented.

(14) I have had my questions answered to my satisfaction.

(15) I consent voluntarily to participate as a participant in the research study.

I am aware, that if I have any questions during this study, I should contact the investigators. By signing this consent from, I attest that the information given in this document has been clearly explained to me and understood by me. I will be given a copy of this consent document.

For adult participants

Name and signature / thumb impression of the participant (or legal representative if participant incompetent):

(Name) _____(Signature)_____ Date: _____

Name and signature of impartial witness (required for illiterate patients):

(Name) _____ (Signature)_____ Date:_____

Address and contact number of the impartial witness: _____

Name and signature of the Investigator or his representative obtaining consent:

(Name) _____ (Signature)_____ (Date)_____

ஆராய்ச்சி ஒப்புதல் படிவம்

பங்குகொள்பவரின் பெயர் :

ஆய்வாளரின் பெயர் :

பங்குபெறும் இடம் : அரசு பொது மருத்துவமனை, சென்னை

நான் இந்த படிவத்தை முழுவதுமாக படித்தேன். என்னுடைய சந்தேகங்களை கேட்டு தெளிவிபடுத்திக்கொண்டேன். தயக்கமில்லாமல் நான் 18 வயதிற்கு மேற்பட்டவர் என்பதையும் இந்த ஆய்வாளர் மேற்கொள்ளும் இந்த ஆய்விற்கு தலைப்பு : துருவ மனசுழற்சி நோயுடையவர்கள் மனம் சீராக இருக்கும்பொழுது ஒரு ஆய்வு – தூக்கம் மற்றும் வாழ்க்கைதரம் பற்றியது என்னை இணைத்துக்கொள்ள முழுசம்மதம் தெரிவிக்கிறேன்.

1. நான் இந்த ஒப்புதல் படிவத்தில் மற்றும் ….. அனைத்தையும் படித்து அறிந்துக்கொண்டேன்.

2. ஒப்புதல் படிவம் முழுவதுமாக எனக்கு விவரிக்கப்பட்டது.

3. இந்த ஆய்வின் தன்மையை பற்றிய விளக்கங்களை அறிந்துக்கொண்டேன்.

4. என்னுடைய உரிமைகளையும் மற்றும் பொறுப்புகள் என்ன என்பதையும் ஆய்வாளர் மூலம் அறிந்துக்கொண்டேன்.

5. நான் எடுத்துக்கொள்ளும் முன்பு எடுத்துக்கொண்ட எல்லா சிகிச்சை முறைகளையும் (இத மருந்து சிகிச்சை உட்பட) ஆய்வாளருக்கு தெரியபடுத்தினேன்

6. இந்த ஆய்வின்ள நாள் பங்குபெறுவதின் மூலம் ஏற்படும் விளைவுகளையும் நான் அறிந்துக்கொண்டேன்.

7. நான் ஆய்வாளருக்கு என் முழு ஒத்துழைப்பையும் அளிப்பேன். மேலும் எனக்கு ஏதேனும் வித்தியாசமான அறிகுறிகள் தென்பட்டால் அதை உடனே ஆய்வாளருக்கு தெரிவிப்பேன்.

8. நான் இதற்கு முன்பு கடந்த _____ மாதங்களில் எந்தவித ஆய்வுகளிலும் பங்குபெறவில்லை.

9. நான் கடந்த _____ மாதங்களில் இரத்த தானம் செய்யவில்லை.

10. நான் எந்த நேரத்திலும் இந்த ஆய்வில் இருந்து வெளியேரலாம் என்றும் இதனால் பிற்காலத்தில் எனக்கு மருத்துமனையில் கொடுக்கப்படும் சிகிச்சையில் எந்த பாதிப்பும் இருக்காது என்பதை அறிந்துள்ளேன்.

11. மேலும், எந்த நேரத்திலும், எந்த காரணத்திற்காவது ஆய்வாளர் இந்த ஆய்வின் பங்காளராய் இருப்பதிலிருந்து என்னை விலக்கிவிடுவார் என்பதையும் அறிந்துள்ளேன்.

12. என்னிடம் இந்த ஆய்வின் மூலம் பெறப்பட்ட தகவல்களின் ஆய்வாளர், உயர் அதிகாரிகளிடம் அரசு இயந்தரங்களிலும் மற்றும் நெறிமுறை குழுவில் தெரியபடுத்த சம்மதிக்கிறேன். அவர்கள் என்னுடைய முழு தகவல்களை ஆராய நேரலாம் என்று அறிந்துக்கொள்ளலாம்.

13. என்னுடைய தகவல்கள் வெளியிடும்பொழுது, என்னுடைய அடையாளங்கள் இரகசியமாக பாதுகாக்கப்படும் என்று புரிந்துகொண்டேன்.

14. என்னுடைய கேள்விகளுக்கு திருப்திகரமான பதில்கள் கிடைத்தல்

15. நான் தானாகவே முன்வந்து இந்த ஆய்வில் என்னை ஒரு உறுப்பினராக இணைத்துக்கொண்டேன்.

இந்த ஆய்வில், எனக்கு ஏதேனும் கேள்விகள் எழுந்தால் அதை ஆய்வாளரிடம் கேட்டு அறிந்துக்கொள்ள வேண்டும் என்பதையும் தெரிந்துக்கொண்டேன். இந்த படிவத்தில் கையெழுத்து இடுவதன் மூலம் இந்த ஆய்வின் எல்லா கருத்துக்களையும் நான் படித்து அறிந்துக்கொண்டேன் என்பதையும் தெரிவித்துக்கொள்கிறேன். இந்த படிவத்தின் நகலையும் நான் பெற்றுக்கொண்டேன்.

ஆராய்ச்சி தகவல் தாள்

தலைப்பு : துருவ மனசுழற்சி நோயுடையவர்கள் மனம் சீராக இருக்கும்பொழுது ஒரு ஆய்வு – தூக்கம் மற்றும் வாழ்க்கைதரம் பற்றியது

ஆய்வாளரின் பெயர் :

பங்குகொள்பவரின் பெயர் :

பங்குபெறும் இடம் : அரசு பொது மருத்துவமனை, சென்னை

ஆராய்ச்சியின் நோக்கம்

இருதுருவ மனசுழற்சி நோயுடையவர்கள், நோயற்ற இருக்கும்பொழுது (மனம் சீராக இருக்கும்பொழுது) அவர்கள் தூக்கம் மற்றும் வாழ்க்கை தரம் பாதிப்பு எந்த அளவு உள்ளது என்று ஒரு ஆய்வு நடைபெறுகிறது. நீங்களும் இந்த ஆராய்ச்சியில் பங்கேற்க விரும்புகிறீர்களா.

இந்த ஆராய்ச்சியின் நோக்கம் : தூக்கம் மற்றும் வாழ்க்கை தரம், ஆரோக்கியமான நபர்களிடம் ஒப்பிட்டு பார்ப்பதல் ஆகும்.

இதனை கண்டறிய உதவும் வினாத்தொகுப்பை உங்களிடம் கேட்டறிந்து அளவிடப்படும்:

1) பிட்ஸ்பர்க் தூக்க தர அளவீடு
2) எட்வொர்க் தூக்க அளவீடு
3) உலக சுகாதார நிறுவனம் – வாழ்க்கைத்தர அளவீடு

இதனால் உங்களுக்கு எந்த பாதிப்பும் ஏற்படாது. உங்களது சிகிச்சை முறையில் மாற்றமும் செய்யப்படமாட்டாது என்றும் இந்த ஆராய்ச்சிக்காக எந்த குறிப்பிட்ட மருந்துகளும் பரிசோதனைக்காகள உபயோகிக்கப்படவில்லை என்று உறுதியளிக்கிறேன்.

முடிவுகளை அல்லது கருத்துக்களை வெளியிடும்போது அல்லது ஆராய்ச்சியின் போதோ தங்களது பெயரையோ அல்லது அடையாளங்களையோ வெளியிடமாட்டோம் என்பதை தெரிவித்துக்கொள்கிறோம்.

இந்த ஆய்வின் முடிவுகள் ஆராய்ச்சியின்போது அல்லது ஆராய்ச்சியின் முடிவின்போது தங்களுக்கு அறிவிக்கப்படும் என்பதையும் தெரிவித்துக் கொள்கிறோம்.

இந்த ஆராய்ச்சியின் பங்கேற்பது தங்களுடைய விருப்பத்தின் பேரில் நான் இருக்கிறது. மேலும் நீங்கள் எந்த நேரமும் இந்த ஆராய்ச்சியிலிருந்து பின்வாங்கலாம் என்பதையும் தெரிவித்துக்கொள்கிறோம்.

ஆராய்ச்சியாளர் கையொப்பம்

நாள் :

இடம்

பங்கேற்பாளர் கையொப்பம் /

இடது கை ரேகை

SEMI – STRUCTURED PROFORMA

IDENTIFICATION DATA OF THE PATIENT :

NAME :

AGE(DOB) :

SEX :

MARITAL STATUS : SINGLE/MARRIED/DIVORCED/WIDOWED

CHILDREN :

EDUCATION :

OCCUPATION :

EMPLOYMENT STATUS : a)FULLTIME/PART TIME/VOLUNTEER/
HOMEMAKER/UNEMPLOYED/STUDENT
b)NIGHT SHIFT

SOCIO-ECONOMIC STATUS :

LANGUAGE :

RELIGION :

ADDRESS :

INFORMANT :

FAMILY HISTORY OF PSYCHIATRIC ILLNESS :

PATERNAL SIDE : GRANDFATHER/GRANDMOTHER/FATHER

MATERNAL SIDE: GRANDFATHER/GRANDMOTHER/MOTHER

SIBLINGS: BROTHERS/SISTERS

CLINICAL MEDICAL COMORBIDITIES :

PSYCHIATRIC COMORBIDITIES :

TREATMENT HISTORY(CLINICAL MEDICATIONS) : 1)
2)
3)

ALCOHOL CONSUMPTION : CURRENT:

PAST :

STYLE :

TOBACCO USE :

COFFEE CONSUMPTION :

STYLE :

USUAL TIME OF COFEE /TEA :

(before going to bed)

Sleep hygiene (SH)	Yes	No
1]Quiet bedroom :		
2]Mattress comfortable :		
3]Alcohol as a sleep aid :		
4]Exercise within 4 hrs of going to bed :		
5]Reading while in bed :		
6]Watching television while in bed :		
7]Using telephone while in bed :		
8] Playing radio while in bed :		
9]Desk with paper work in bedroom :		
10]Tea / coffee / caffeinated soft drinks after 5 pm :		
11]Cigarettes after 5 pm :		
12] Standard cups of tea/ day		
13] Standard cups of coffee / day :		
14] Standared cups of caffeinated drinks / day		
15] Number of cigarettes /day :		

CLINICAL VARIABLES ASSESSED IN BD SAMPLES:

1] DURATION OF ILLNESS :

2] NUMBER OF HOSPITALISATION :

3] AGE AT ONSET OF ILLNESS :

4] AGE OF 1ST MANIC EPISODE :

5] AGE OF FIRST DEPRESSIVE EPISODE :

6] NO. OF MANIC/MIXED EPISODES :

7] NO.OF DEPRESSIVE EPISODE :

8] NO OF RAPID CYCLE PATIENTS :

9] LAST EPISODE (MANIC/DEPRESSIVE) OCCURRENCE :

10] SUICIDE ATTEMPTS :

11] NO.OF ATTEMPTS :

12] AGE OF FIRST ATTEMPT :

13] MEDICATIONS :

SlNo	Group	Age (years)	\	Marital status	Children	Education	Occupation	Employement Status	Socio Economic Status	Language	Religion	Address	Informant	Family History	CMI - Medical	CMI - Psychiatric
1	Cases	28	Male	Single	Nil	Graduate	Semiskilled	Full time	Lower Middle	Tamil	Hindu	Semi-Urban	Self	Nil	No	No
2	Cases	59	Male	Married	Nil	High	Semiskilled	Part time	Upper Lower	Others	Hindu	Semi-Urban	Others	Nil	No	No
3	Cases	24	Female	Married	Nil	Graduate	Unemployed	Home maker	Upper Lower	Tamil	Christian	Urban	Others	Nil	No	No
4	Cases	56	Female	Married	Four	Primary	Unemployed	Home maker	Upper Lower	Tamil	Muslim	Semi-Urban	Others	Nil	No	No
5	Cases	57	Male	Married	Three	High	Unskilled	Night shift	Upper Lower	Tamil	Hindu	Semi-Urban	Self	Nil	No	No
6	Cases	38	Female	Married	Two	High	Semiskilled	Full time	Upper Lower	Tamil	Hindu	Semi-Urban	Self	Nil	No	No
7	Cases	45	Female	Married	Three	Middle	Unemployed	Home maker	Upper Lower	Tamil	Hindu	Rural	Self	Nil	No	No
8	Cases	37	Male	Married	One	Middle	Semiskilled	Full time	Upper Lower	Tamil	Hindu	Semi-Urban	Others	Nil	No	No
9	Cases	52	Female	Married	Three	Middle	Unskilled	Part time	Upper Lower	Tamil	Hindu	Rural	Others	Nil	No	No
10	Cases	31	Male	Single	Nil	Middle	Unskilled	Full time	Lower	Tamil	Hindu	Semi-Urban	Self	Nil	No	No
11	Cases	35	Female	Married	Two	Primary	Unskilled	Part time	Lower	Others	Hindu	Rural	Others	Nil	No	No
12	Cases	26	Female	Single	Nil	High	Unskilled	Full time	Upper Lower	Tamil	Christian	Urban	Self	Nil	No	No
13	Cases	46	Male	Married	Three	Iliterate	Unskilled	Full time	Lower	Tamil	Hindu	Semi-Urban	Self	Nil	No	No
14	Cases	19	Male	Single	Nil	High	Unemployed	Unemployed	Lower	Tamil	Hindu	Semi-Urban	Others	Father	No	No
15	Cases	44	Male	Married	One	High	Unskilled	Full time	Lower	Tamil	Hindu	Rural	Self	Nil	No	No
16	Cases	37	Male	Married	Nil	Graduate	Semiskilled	Full time	Lower Middle	Tamil	Christian	Semi-Urban	Others	Nil	No	No
17	Cases	29	Male	Single	Nil	Graduate	Skilled	Full time	Lower Middle	Tamil	Hindu	Semi-Urban	Self	Nil	No	No
18	Cases	50	Male	Married	Nil	High	Semiskilled	Part time	Upper Lower	Tamil	Hindu	Semi-Urban	Others	Nil	No	No
19	Cases	23	Female	Married	Nil	Graduate	Semiskilled	Full time	Lower Middle	Tamil	Hindu	Urban	Others	Nil	No	No
20	Cases	54	Female	Married	Four	Primary	Unemployed	Home maker	Upper Lower	Others	Muslim	Semi-Urban	Others	Nil	No	No
21	Cases	58	Male	Married	Three	High	Unskilled	Full time	Upper Lower	Tamil	Hindu	Semi-Urban	Self	Nil	No	No
22	Cases	36	Female	Married	Two	High	Semiskilled	Full time	Upper Lower	Tamil	Hindu	Semi-Urban	Self	Nil	No	No
23	Cases	43	Female	Married	Three	High	Unemployed	Home maker	Upper Lower	Tamil	Hindu	Semi-Urban	Self	Nil	No	No
24	Cases	35	Male	Married	One	Middle	Unskilled	Full time	Upper Lower	Tamil	Hindu	Semi-Urban	Others	Nil	No	No
25	Cases	50	Female	Married	Three	Middle	Unskilled	Part time	Upper Lower	Tamil	Hindu	Semi-Urban	Others	Nil	No	No
26	Cases	28	Male	Single	Nil	Middle	Unskilled	Full time	Upper Lower	Tamil	Hindu	Semi-Urban	Self	Nil	No	No
27	Cases	33	Female	Married	Two	Primary	Unskilled	Part time	Upper Lower	Others	Hindu	Semi-Urban	Others	Nil	No	No
28	Cases	24	Female	Single	Nil	High	Unskilled	Full time	Upper Lower	Tamil	Christian	Semi-Urban	Self	Nil	No	No
29	Cases	44	Male	Married	Three	Iliterate	Unskilled	Full time	Upper Lower	Tamil	Hindu	Semi-Urban	Self	Nil	No	No

30	Cases	22	Male	Single	Nil	High	Unemployed	Unemployed	Upper Lower	Tamil	Hindu	Semi-Urban	Others	Father	No	No
31	Cases	42	Male	Married	One	High	Unskilled	Full time	Upper Lower	Tamil	Hindu	Semi-Urban	Self	Nil	No	No
32	Cases	35	Male	Married	Nil	Graduate	Semiskilled	Full time	Lower Middle	Tamil	Christian	Semi-Urban	Others	Nil	No	No
33	Cases	30	Male	Single	Nil	High	Unskilled	Full time	Upper Lower	Tamil	Hindu	Semi-Urban	Self	Nil	No	No
34	Cases	34	Female	Married	Two	Middle	Unskilled	Part time	Upper Lower	Others	Hindu	Semi-Urban	Others	Nil	No	No
35	Cases	25	Female	Single	Nil	High	Unskilled	Full time	Upper Lower	Tamil	Christian	Semi-Urban	Self	Nil	No	No
36	Cases	45	Male	Married	Three	Iliterate	Unskilled	Full time	Upper Lower	Tamil	Hindu	Semi-Urban	Self	Nil	No	No
37	Cases	20	Female	Single	Nil	High	Unemployed	Unemployed	Upper Lower	Tamil	Hindu	Semi-Urban	Others	Father	No	No
38	Cases	46	Female	Married	One	High	Unskilled	Full time	Upper Lower	Tamil	Hindu	Semi-Urban	Self	Nil	No	No
39	Cases	35	Male	Married	Nil	Graduate	Skilled	Full time	Lower Middle	Tamil	Christian	Semi-Urban	Others	Nil	No	No
40	Cases	31	Male	Single	One	Graduate	Skilled	Full time	Lower Middle	Tamil	Hindu	Urban	Self	Nil	No	No
41	Cases	58	Male	Married	Nil	High	Semiskilled	Part time	Upper Lower	Others	Hindu	Semi-Urban	Others	Nil	No	No
42	Cases	24	Female	Married	Nil	Graduate	Unemployed	Home maker	Upper Lower	Tamil	Christian	Semi-Urban	Others	Nil	No	No
43	Cases	56	Female	Married	Four	Primary	Unemployed	Home maker	Upper Lower	Others	Muslim	Semi-Urban	Others	Nil	No	No
44	Cases	57	Male	Married	Three	High	Semiskilled	Night shift	Upper Lower	Tamil	Hindu	Semi-Urban	Self	Nil	No	No
45	Cases	38	Female	Married	Two	High	Semiskilled	Full time	Upper Lower	Tamil	Hindu	Semi-Urban	Self	Nil	No	No
46	Cases	45	Female	Married	Three	Middle	Unemployed	Home maker	Upper Lower	Tamil	Hindu	Semi-Urban	Self	Nil	No	No
47	Cases	37	Male	Married	One	Middle	Unskilled	Full time	Upper Lower	Tamil	Hindu	Semi-Urban	Others	Nil	No	No
48	Cases	52	Female	Married	Three	Middle	Unskilled	Part time	Upper Lower	Tamil	Hindu	Semi-Urban	Others	Nil	No	No
49	Cases	56	Female	Married	Three	Primary	Unemployed	Home maker	Upper Lower	Others	Muslim	Semi-Urban	Others	Nil	No	No
50	Cases	31	Male	Single	Nil	Middle	Unskilled	Full time	Upper Lower	Tamil	Hindu	Semi-Urban	Self	Nil	No	No

Alcohol consumption	Tobacco use	Coffee / Tea	Frequency of Coffee/Tea	Before Bed	SH-01. Quiet bedroom	SH-02. Mattress comfortable	SH-03. Alcohol as a sleep aid	SH-04. Exercise within 4 hrs of	SH-05. Reading while in	SH-06. Watching television	SH-07. Using telepho	SH-08. Playing radio	SH-09. Desk with paper	SH-10. Tea / coffee / caffe	SH-11. Cigarettes after 5 pm	SH-12. Standard cups of tea/ day	SH-13. Standard cups of coffee / day	SH-14. Standard cups of coffeinated drinks / day	SH-15. Number of cigarettes /day	Duration of illness (years)	Number of hospitalisation	Age at onset of illness(years)	Age of 1st manic episode(years)
No	No	Tea	2 - 4 times	After 5 pm	Yes	Yes	No	Yes	No	Yes	Yes	Yes	No	Yes	No	2 - 4 times	0 time	0 time	0 time	11	Four	17	17
No	Yes	Tea	2 - 4 times	Before 5 pm	Yes	Yes	No	No	No	Yes	No	Yes	No	No	Yes	2 - 4 times	0 time	0 time	> 4 times	29	Two	30	30
No	No	Coffee	2 - 4 times	Before 5 pm	Yes	Yes	No	No	No	Yes	No	No	No	Yes	No	0 time	2 - 4 times	0 time	0 time	6	One	18	18
No	No	Tea	2 - 4 times	After 5 pm	Yes	Yes	No	No	No	No	No	No	No	Yes	No	0 time	2 - 4 times	0 time	0 time	30	One	26	36
No	No	Coffee	2 - 4 times	Before 5 pm	Yes	Yes	No	No	No	Yes	No	No	No	Yes	No	0 time	< 2 times	0 time	0 time	34	One	23	23
No	No	Coffee	2 - 4 times	Before 5 pm	Yes	Yes	No	No	No	No	Yes	Yes	No	Yes	Yes	0 time	2 - 4 times	0 time	0 time	13	Two	25	28
No	No	Coffee	2 - 4 times	Before 5 pm	Yes	Yes	No	No	No	Yes	No	No	No	Yes	No	0 time	2 - 4 times	0 time	0 time	10	One	35	35
No	No	Coffee	2 - 4 times	After 5 pm	Yes	Yes	No	No	No	Yes	Yes	Yes	No	Yes	No	0 time	2 - 4 times	0 time	0 time	8	Nil	29	32
No	No	Tea	< 2 times	Before 5 pm	Yes	Yes	No	No	No	Yes	No	No	No	Yes	No	< 2 times	0 time	0 time	0 time	10	Two	42	44
No	Yes	Tea	> 4 times	After 5 pm	Yes	Yes	No	No	No	No	No	No	No	No	No	> 4 times	0 time	0 time	> 4 times	9	Two	22	22
No	No	Tea	< 2 times	Before 5 pm	Yes	Yes	No	No	No	No	No	Yes	No	No	No	< 2 times	0 time	0 time	0 time	3	Nil	32	32
No	No	Coffee	< 2 times	Before 5 pm	Yes	Yes	No	No	No	Yes	No	No	No	No	No	0 time	< 2 times	0 time	0 time	12	Four	14	14
No	No	Coffee	2 - 4 times	After 5 pm	Yes	Yes	No	No	No	No	No	No	No	No	No	0 time	2 - 4 times	0 time	0 time	30	Five	16	20
No	No	Coffee	2 - 4 times	After 5 pm	Yes	Yes	No	No	No	Yes	No	No	No	No	No	0 time	2 - 4 times	0 time	0 time	4	One	15	18
No	No	Coffee	2 - 4 times	After 5 pm	Yes	Yes	No	No	No	No	No	No	No	No	No	0 time	2 - 4 times	0 time	0 time	24	One	20	20
No	No	Tea	2 - 4 times	After 5 pm	Yes	Yes	No	No	No	No	Yes	No	No	No	No	2 - 4 times	0 time	0 time	0 time	18	Five	19	19
No	No	Tea	2 - 4 times	After 5 pm	Yes	Yes	No	Yes	No	Yes	Yes	Yes	No	Yes	No	2 - 4 times	0 time	0 time	0 time	13	Three	16	16
No	Yes	Tea	2 - 4 times	Before 5 pm	Yes	Yes	No	No	No	Yes	No	Yes	No	No	Yes	2 - 4 times	0 time	0 time	> 4 times	20	Two	30	30
No	No	Coffee	2 - 4 times	Before 5 pm	Yes	Yes	No	No	No	Yes	No	No	No	Yes	No	0 time	2 - 4 times	0 time	0 time	4	One	19	19
No	No	Tea	2 - 4 times	After 5 pm	Yes	Yes	No	No	No	No	No	No	No	Yes	No	0 time	2 - 4 times	0 time	0 time	28	One	26	36
No	No	Coffee	2 - 4 times	Before 5 pm	Yes	Yes	No	No	No	Yes	No	No	No	Yes	No	0 time	< 2 times	0 time	0 time	33	One	25	25
No	No	Coffee	2 - 4 times	Before 5 pm	Yes	Yes	No	No	No	No	Yes	Yes	No	Yes	Yes	0 time	2 - 4 times	0 time	0 time	10	Two	26	28
No	No	Coffee	2 - 4 times	Before 5 pm	Yes	Yes	No	No	No	Yes	No	No	No	Yes	No	0 time	2 - 4 times	0 time	0 time	8	One	35	35
No	No	Coffee	2 - 4 times	After 5 pm	Yes	Yes	No	No	No	Yes	Yes	Yes	No	Yes	No	0 time	2 - 4 times	0 time	0 time	6	Nil	29	32
No	No	Tea	< 2 times	Before 5 pm	Yes	Yes	No	No	No	Yes	No	No	No	Yes	No	< 2 times	0 time	0 time	0 time	10	Two	42	44
No	Yes	Tea	> 4 times	After 5 pm	Yes	Yes	No	No	No	No	No	No	No	No	No	> 4 times	0 time	0 time	> 4 times	7	Two	21	21
No	No	Tea	< 2 times	Before 5 pm	Yes	Yes	No	No	No	No	No	Yes	No	No	No	< 2 times	0 time	0 time	0 time	3	Nil	30	30
No	No	Coffee	< 2 times	Before 5 pm	Yes	Yes	No	No	No	Yes	No	No	No	No	No	0 time	< 2 times	0 time	0 time	10	Four	14	14
No	No	Coffee	2 - 4 times	After 5 pm	Yes	Yes	No	No	No	No	No	No	No	No	No	0 time	2 - 4 times	0 time	0 time	24	Five	20	20

No	No	Coffee	2 - 4 times	After 5 pm	Yes	Yes	No	No	No	Yes	No	No	No	No	No	0 time	2 - 4 times	0 time	0 time	5	One	17	18
No	No	Coffee	2 - 4 times	After 5 pm	Yes	Yes	No	No	No	No	No	No	No	No	No	0 time	2 - 4 times	0 time	0 time	22	One	20	20
No	No	Tea	2 - 4 times	After 5 pm	Yes	Yes	No	No	No	No	Yes	No	No	No	No	2 - 4 times	0 time	0 time	0 time	15	Five	20	20
No	Yes	Tea	> 4 times	After 5 pm	Yes	Yes	No	No	No	No	No	No	No	No	No	> 4 times	0 time	0 time	> 4 times	10	Two	20	20
No	No	Tea	< 2 times	Before 5 pm	Yes	Yes	No	No	No	No	No	Yes	No	No	No	< 2 times	0 time	0 time	0 time	3	Nil	31	31
No	No	Coffee	< 2 times	Before 5 pm	Yes	Yes	No	No	No	Yes	No	No	No	No	No	0 time	< 2 times	0 time	0 time	11	Four	14	14
No	No	Coffee	2 - 4 times	After 5 pm	Yes	Yes	No	No	No	No	No	No	No	No	No	0 time	2 - 4 times	0 time	0 time	29	Five	16	20
No	No	Coffee	2 - 4 times	After 5 pm	Yes	Yes	No	No	No	Yes	No	No	No	No	No	0 time	2 - 4 times	0 time	0 time	5	One	15	18
No	No	Coffee	2 - 4 times	After 5 pm	Yes	Yes	No	No	No	No	No	No	No	No	No	0 time	2 - 4 times	0 time	0 time	26	One	20	20
No	No	Tea	2 - 4 times	After 5 pm	Yes	Yes	No	No	No	No	Yes	No	No	No	No	2 - 4 times	0 time	0 time	0 time	17	Five	18	18
No	No	Tea	2 - 4 times	After 5 pm	Yes	Yes	No	Yes	No	Yes	Yes	Yes	No	Yes	No	2 - 4 times	0 time	0 time	0 time	14	Four	17	17
No	Yes	Tea	2 - 4 times	Before 5 pm	Yes	Yes	No	No	No	Yes	No	Yes	No	No	Yes	2 - 4 times	0 time	0 time	> 4 times	28	Two	30	30
No	No	Coffee	2 - 4 times	Before 5 pm	Yes	Yes	No	No	No	Yes	No	No	No	Yes	No	0 time	2 - 4 times	0 time	0 time	6	One	18	18
No	No	Tea	2 - 4 times	After 5 pm	Yes	Yes	No	No	No	No	No	No	No	Yes	No	0 time	2 - 4 times	0 time	0 time	30	One	26	36
No	No	Coffee	2 - 4 times	Before 5 pm	Yes	Yes	No	No	No	Yes	No	No	No	Yes	No	0 time	< 2 times	0 time	0 time	34	One	23	23
No	No	Coffee	2 - 4 times	Before 5 pm	Yes	Yes	No	No	No	No	Yes	Yes	No	Yes	Yes	0 time	2 - 4 times	0 time	0 time	13	Two	25	28
No	No	Coffee	2 - 4 times	Before 5 pm	Yes	Yes	No	No	No	Yes	No	No	No	Yes	No	0 time	2 - 4 times	0 time	0 time	10	One	35	35
No	No	Coffee	2 - 4 times	After 5 pm	Yes	Yes	No	No	No	Yes	Yes	Yes	No	Yes	No	0 time	2 - 4 times	0 time	0 time	8	Nil	29	32
No	No	Tea	< 2 times	Before 5 pm	Yes	Yes	No	No	No	Yes	No	No	No	Yes	No	< 2 times	0 time	0 time	0 time	10	Two	42	44
No	No	Tea	2 - 4 times	After 5 pm	Yes	Yes	No	No	No	No	No	No	No	Yes	No	0 time	2 - 4 times	0 time	0 time	30	One	26	36
No	Yes	Tea	> 4 times	Nil	Yes	Yes	No	No	No	No	No	No	No	No	No	> 4 times	0 time	0 time	> 4 times	9	Two	22	22

Age of first depressive episo	No. of manic/ mixed episodes	No.of depressive episodes	Average episode duration	Rapid cycle patients	Last episode (manic/depressive) occurrence	Suicide attempts	Number of attempts	Age of first attempt	MEDICATIONS	Hamilton Rating Scale for	Young Mania Rating Scale	PSQI Component-1	PSQI Component-2	PSQI Component-3	PSQI Component-4	PSQI Component-5	PSQI Component-6	PSQI Component-7	PSQI Global	Epworth Sleepiness Scale	Physical health domain	Psychological domain	Social relationship domain	Environment domain	Overall perception of quality of life	Overall perception of health
52	Four	One	Three	No	Before 6 - 12 m	No	Nil	Nil	1,6,3	0	0	1	1	1	0	0	3	2	8	4	46.43	50.00	66.67	65.63	50.00	50.00
52	One	One	Six or mor	No	> 60 months	Yes	One	21 - 30 yea	1,6,2	1	1	2	3	1	1	1	3	1	12	2	46.43	50.00	50.00	59.38	75.00	75.00
18	Three	One	Three	No	Before 6 - 12 m	No	Nil	Nil	1,2,6	1	0	1	2	0	0	1	3	2	9	6	50.00	45.83	58.33	71.88	75.00	75.00
26	Six or mo	One	One	No	Before 6 - 12 m	No	Nil	Nil	1,1,2,6	3	2	3	2	1	3	1	3	3	17	4	39.29	50.00	66.67	68.75	50.00	25.00
32	Three	One	Three	No	Before 24 - 60 r	No	Nil	Nil	1,2	0	0	1	1	0	0	1	3	0	6	4	60.71	54.17	50.00	62.50	75.00	75.00
25	One	Two	Three	No	> 60 months	Yes	One	21 - 30 yea	1,3	3	1	1	2	1	0	1	0	2	7	9	53.57	37.50	41.67	59.38	50.00	75.00
nil	Three	Nil	Two	No	Before 24 - 60 r	No	Nil	Nil	2	3	4	1	2	2	1	0	3	1	10	2	46.43	37.50	50.00	62.50	75.00	75.00
29	One	Two	Three	No	Before 24 - 60 r	No	Nil	Nil	1,3,4,6	0	0	1	1	0	1	1	3	1	8	4	39.29	16.67	33.33	46.88	25.00	25.00
42	Three	One	One	No	Before 24 - 60 r	No	Nil	Nil	1,2	4	1	2	3	1	1	0	3	3	13	8	32.14	41.67	50.00	62.50	75.00	50.00
nil	Four	Nil	Three	No	Before 24 - 60 r	No	Nil	Nil	1,2	5	2	3	1	3	1	1	3	1	13	0	42.86	50.00	75.00	65.63	75.00	75.00
33	One	One	Three	No	Before 24 - 60 r	Yes	One	21 - 30 yea	1,2,4	4	1	2	2	0	0	1	2	1	8	0	32.14	45.83	50.00	62.50	50.00	50.00
nil	Four	Nil	Two	No	Before 24 - 60 r	No	Nil	Nil	2	1	0	1	1	0	0	0	1	0	3	4	53.57	58.33	58.33	59.38	75.00	75.00
25	Three	Two	Four	No	Before 24 - 60 r	No	Nil	Nil	1,12,6	3	0	1	2	0	1	0	3	1	8	1	46.43	41.67	58.33	59.38	50.00	50.00
14	One	One	Three	No	Before 12 - 24 r	No	Nil	Nil	1,2,3	0	0	1	2	1	3	1	3	1	12	0	50.00	54.17	50.00	59.38	50.00	75.00
41	Four	One	Three	No	Before 24 - 60 r	No	Nil	Nil	1,2,6	0	0	1	3	0	2	5	3	0	14	3	64.29	50.00	75.00	65.63	75.00	75.00
nil	Five	Nil	Four	No	> 60 months	No	Nil	Nil	2,3	2	0	0	0	0	0	0	0	1	1	5	53.57	62.50	75.00	62.50	75.00	75.00
16	Three	One	Three	No	Before 6 - 12 m	No	Nil	Nil	1,3,6	0	0	1	1	1	0	0	3	2	8	4	46.43	50.00	66.67	65.63	50.00	50.00
42	One	One	Six or mor	No	> 60 months	Yes	One	21 - 30 yea	1,1,2,6	1	1	2	3	1	1	1	3	1	12	2	46.43	50.00	50.00	59.38	75.00	75.00
19	Three	One	Three	No	Before 6 - 12 m	No	Nil	Nil	1,2,6	1	0	1	2	0	0	1	3	2	9	6	50.00	45.83	58.33	71.88	75.00	75.00
26	Six or mo	One	One	No	Before 6 - 12 m	No	Nil	Nil	1,1,2,6	3	2	3	2	1	3	1	3	3	17	4	39.29	50.00	66.67	68.75	50.00	25.00
32	Three	One	Three	No	Before 24 - 60 r	No	Nil	Nil	1,2	0	0	1	1	0	0	1	3	0	6	4	60.71	54.17	50.00	62.50	75.00	75.00
26	One	Two	Three	No	> 60 months	Yes	One	21 - 30 yea	1,3	3	1	1	2	1	0	1	0	2	7	9	53.57	37.50	41.67	59.38	50.00	75.00
nil	Three	Nil	Two	No	Before 24 - 60 r	No	Nil	Nil	2	3	4	1	2	2	1	0	3	1	10	2	46.43	37.50	50.00	62.50	75.00	75.00
29	One	Two	Three	No	Before 24 - 60 r	No	Nil	Nil	1,3,4,6	0	0	1	1	0	1	1	3	1	8	4	39.29	16.67	33.33	46.88	25.00	25.00
42	Three	One	One	No	Before 12 - 24 r	No	Nil	Nil	1,2	4	1	2	3	1	1	0	3	3	13	8	32.14	41.67	50.00	62.50	75.00	50.00
nil	Four	Nil	Three	No	Before 12 - 24 r	No	Nil	Nil	1,2	5	2	3	1	3	1	1	3	1	13	0	42.86	50.00	75.00	65.63	75.00	75.00
31	One	One	Three	No	Before 12 - 24 r	Yes	One	21 - 30 yea	1,2,4	4	1	2	2	0	0	1	2	1	8	0	32.14	45.83	50.00	62.50	50.00	50.00
nil	Four	Nil	Two	No	Before 24 - 60 r	No	Nil	Nil	2	1	0	1	1	0	0	0	1	0	3	4	53.57	58.33	58.33	59.38	75.00	75.00
24	Three	Two	Four	No	Before 24 - 60 r	No	Nil	Nil	1,1,2,6	3	0	1	2	0	1	0	3	1	8	1	46.43	41.67	58.33	59.38	50.00	50.00

17	One	One	Three	No	Before 24 - 60 r	No	Nil	Nil	1,2,3	0	0	1	2	1	3	1	3	1	12	0	50.00	54.17	50.00	59.38	50.00	75.00
39	Four	One	Three	No	Before 24 - 60 r	No	Nil	Nil	1,2,6	0	0	1	3	0	2	5	3	0	14	3	64.29	50.00	75.00	65.63	75.00	75.00
nil	Five	Nil	Four	No	> 60 months	No	Nil	Nil	2,3	2	0	0	0	0	0	0	0	1	1	5	53.57	62.50	75.00	62.50	75.00	75.00
nil	Four	Nil	Three	No	Before 12 - 24 r	No	Nil	Nil	1,2	5	2	3	1	3	1	1	3	1	13	0	42.86	50.00	75.00	65.63	75.00	75.00
32	One	One	Three	No	Before 12 - 24 r	Yes	One	21 - 30 yea	1,2,4	4	1	2	2	0	0	1	2	1	8	0	32.14	45.83	50.00	62.50	50.00	50.00
nil	Four	Nil	Two	No	Before 24 - 60 r	No	Nil	Nil	2	1	0	1	1	0	0	0	1	0	3	4	53.57	58.33	58.33	59.38	75.00	75.00
25	Three	Two	Four	No	Before 24 - 60 r	No	Nil	Nil	1,2,6	3	0	1	2	0	1	0	3	1	8	1	46.43	41.67	58.33	59.38	50.00	50.00
14	One	One	Three	No	Before 12 - 24 r	No	Nil	Nil	1,2	0	0	1	2	1	3	1	3	1	12	0	50.00	54.17	50.00	59.38	50.00	75.00
41	Four	One	Three	No	Before 24 - 60 r	No	Nil	Nil	1,2,6	0	0	1	3	0	2	5	3	0	14	3	64.29	50.00	75.00	65.63	75.00	75.00
nil	Five	Nil	Four	No	> 60 months	No	Nil	Nil	2,3	2	0	0	0	0	0	0	0	1	1	5	53.57	62.50	75.00	62.50	75.00	75.00
17	Four	One	Three	No	Before 6 - 12 m	No	Nil	Nil	1,3,6	0	0	1	1	1	0	0	3	2	8	4	46.43	50.00	66.67	65.63	50.00	50.00
52	One	One	Six or mor	No	> 60 months	Yes	One	21 - 30 yea	1,2,6	1	1	2	3	1	1	1	3	1	12	2	46.43	50.00	50.00	59.38	75.00	75.00
18	Three	One	Three	No	Before 6 - 12 m	No	Nil	Nil	1,2	1	0	1	2	0	0	1	3	2	9	6	50.00	45.83	58.33	71.88	75.00	75.00
26	Six or mo	One	One	No	Before 6 - 12 m	No	Nil	Nil	1,2,3	3	2	3	2	1	3	1	3	3	17	4	39.29	50.00	66.67	68.75	50.00	25.00
32	Three	One	Three	No	Before 24 - 60 r	No	Nil	Nil	1,2	0	0	1	1	0	0	1	3	0	6	4	60.71	54.17	50.00	62.50	75.00	75.00
25	One	Two	Three	No	> 60 months	Yes	One	21 - 30 yea	1,3	3	1	1	2	1	0	1	0	2	7	9	53.57	37.50	41.67	59.38	50.00	75.00
nil	Three	Nil	Two	No	Before 24 - 60 r	No	Nil	Nil	2	3	4	1	2	2	1	0	3	1	10	2	46.43	37.50	50.00	62.50	75.00	75.00
29	One	Two	Three	No	Before 24 - 60 r	No	Nil	Nil	1,2,4,6	0	0	1	1	0	1	1	3	1	8	4	39.29	16.67	33.33	46.88	25.00	25.00
42	Three	One	One	No	Before 12 - 24 r	No	Nil	Nil	1,2	4	1	2	3	1	1	0	3	3	13	8	32.14	41.67	50.00	62.50	75.00	50.00
26	Six or mo	One	One	No	Before 6 - 12 m	No	Nil	Nil	1,2	3	2	3	2	1	3	1	3	3	17	4	39.29	50.00	66.67	68.75	50.00	25.00
nil	Four	Nil	Three	No	Before 12 - 24 r	No	Nil	Nil	1,2	5	2	3	1	3	1	1	3	1	13	0	42.86	50.00	75.00	65.63	75.00	75.00

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MINI PLUS

M.I.N.I. Plus 5.0.0

Patient's Initials: ☐☐☐ Patient's ID Number (PID): ☐☐☐☐☐☐

Data Entrant (initials): ☐☐☐ Date (Day/Month/Year) ☐☐ / ☐☐ / ☐☐☐☐

Rater's Initials: ☐☐☐

MODULES	TIME FRAME	DSM-IV	ICD-10	Page	Meets Criteria
A. Major Depressive Episode	Current (2 weeks)	296.20-296.26 single	F32.x	3	☐
	Recurrent	296.30-296.36 recurrent	F33.x	4	
Mood Disorder due to a	Current	293.83	F06.xx		☐
Medical Condition	Past	293.83	none	4	
Substance Induced Mood	Current	29x.xx	none		☐
Disorder	Past	29x.xx	none		
MDE with Melancholic	Current (2 weeks)	296.20-296.26 single	F32.x	5	☐
B. Dysthymia	Current (past 2 years)	300.4	F34.1	6	☐
	Past	300.4	F34.1		
C. Suicidality	Current (past month)	none	none	7	☐
	Risk: ____ Low ____Medium ____High				
D. Manic Episode	Current	296.00-296.06	F30.x-F31.9	8	☐
	Past	296.00-296.06	F30.x-F31.9		
Hypomanic Episode	Current	296.80-296.89	F31.8-F31.9/F34.0	8	☐
	Past	296.80-296.89	F31.8-F31.9/F34.0		
Bipolar II Disorder	Current	296.89	F31.8		☐
	Past	296.89	F31.8		
Manic Episode due to a	Current	293.83	F06.30		☐
Medical Condition	Past	293.83	F06.30		
Hypomanic Episode due to	Current	293.83	none		☐
a Medical Condition	Past	293.83	none		
Substance Induced Manic	Current	291.8-292-84	none		☐
Episode	Past	291.8-292-84	none		
Substance Induced	Current	291.8-292.84	none		☐
Hypomanic Episode	Past	291.8-292.84	none		
E. Panic Disorder	Current (past month)	291.8-292.84	none	11	☐
Anxiety Disorder with Panic	Current	293.89	F06.4	12	☐
due to a General Med. Condition					
Substance induced Anxiety	Current	291.8-292.89	none	12	☐
Disorder with Panic Attacks					
F. Agoraphobia	Current	300.22	F40.00	13	☐
G. Social Phobia (Soc.AnxDis.)	Current(past month)	300.23	F40.1	14	
H. Specific Phobia	Current	300.3	F42.8	15	☐
OCD due to general medical	Current	293.89	F06.4	16	☐
condition					
Substance induced OCD	Current	291.8-292.89	none	16	
I. Obsessive-Compulsive Disorder	Current (past month)	300.3	F42.8		☐
J. Posttraumatic Stress Disorder	Current (past month)	309.81	F43.1	17	☐
K. Alcoholic Dependence	Past 12 months	303.9	F10.2x	18	☐
Alcoholic Dependence	Lifetime	303.9	F10.2x	19	☐
Alcoholic Abuse	Past 12 months	305.9	F10.1	18	☐
Alcoholic Abuse	Lifetime	305.00	F10.1	18	☐
L. Substance Dependence	Past 12 months	304.00-.9/305.20-.90	F11.0-F19.1	20	☐
(non-alcohol)					☐
Substance Dependence(non-alcohol)	Lifetime	304.00-.9/305.20-.90	F11.0-F19.1	20	
M. Psychotic Disorders	Lifetime	295.10-295.90//297.1/	F20.xx.F29	24	☐
	Current	297.3/297.81/293.82/		24	
		293.89/298.8/298.9			
Mood Disorder with Psychotic	Current	296.24	F32.3/F33.3	29	☐
Features					

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MODULES	TIME FRAME	DSM-IV	ICD-10	Page	Meet Criteria
Schizophrenia	Current	295.10-295.60	F20.xx		☐
	Lifetime	295.10-295.60	F20.xx		
Schizoaffective Disorder	Current	295.70	F25..x		☐
	Lifetime	295.70	F25.x		
Schizophreniform Disorder	Current	295.40	F20.8		☐
	Lifetime	295.40	F20.8		
Brief Psychotic Disorder	Current	298.8	F23.80-F23.81		☐
	Lifetime	298.8	F23.80-F23.81		
Delusional Disorder	Current	297.1	F22.0		☐
	Lifetime	297.1	F22.0		
Psychotic Disorder due to a General Medical Condition	Current	293.xx	F06.0-F06.2		☐
	Lifetime	293.xx	F06.0-F06.2		
Substance Induced Psychotic Disorder	Current	291.5-292.12	none		☐
	Lifetime	291.5-292.12	none		☐
Psychotic Disorder NOS	Current	298.9	F29		☐
	Lifetime	298.9	F29		
Mood Disorder with Psychotic Features	Lifetime		F31.X3/F31.X2/		☐
			F31.X5		☐
Mood Disorder NOS	Lifetime	296.90	F39		☐
Major Depressive Disorder with Psychotic Features	Current	296.24	F33.X3		☐
	Past	296.24	F33.X3		
Bipolar I Disorder with Psychotic Features	Current	296.04-296.64	F31.X2/F31.X5		☐
	Past	296.04-296.64	F31.X2/F31.X5		
N. Anorexia Nervosa	Current (past 3 months)	307.1	F50.0	30	☐
O. Bulimia Nervosa	Current (past 3 months)	307.51	F50.2	32	☐
Bulimia Nervosa Purging Type	Current	307.51	F50.2		☐
Bulimia Nervosa Non-Purging Type	Current	307.51	F50.2		☐
Anorexia Nervosa, Binge Eating/ Purging Type	Current	307.1	F50.0		☐
					☐
Anorexia Nervosa, Restricting Type	Current	307.1	F50.0		☐
P. Generalized Anxiety Disorder	Current (past 6 months)	300.02	F41.1	34	☐
Generalized Anxiety Disorder due to a General Medical Condition	Current	293.89	F06.4		☐
Substance induced GAD	Current	291.8-292.89	none		☐
Q. Antisocial Personality Disorder	Lifetime	301.7	F60.2	36	☐
R. Somatization Disorder	Lifetime	330.81	F45.0	37	☐
	Current				
S. Hypochondriasis	Current	300.7	F45.2	38	☐
T. Body Dysmorphic Disorder	Lifetime	300.7	F45.2	39	☐
U. Pain Disorder	Current	300.89/307.8	F45.4	39	☐
V. Conduct Disorder	Past 12 months	312.8	F91.8	40	☐
W. Attention Deficit/Hyperactivity Disorder (children/adolescents)	Past 6 months	314.00/314.01	F90.0/F90.9/ F98.8	41	☐
Attention Deficit Hyperactivity Disorder (adults)	Lifetime	314.00/314.01	F90.0/F98.8	42	☐
X. Adjustment Disorders	Current	309.xx		43	☐
Y. Premenstrual Dysphoric Disorder	Current			44	☐
Z. Mixed Anxiety-Depressive Disorder	Current			45	☐

THE HAMILTON RATING SCALE FOR DEPRESSION

(to be administered by a health care professional)

Patient's Name _____

Date of Assessment _____

To rate the severity of depression in patients who are already diagnosed as depressed, administer this questionnaire. The higher the score, the more severe the depression.

For each item, write the correct number on the line next to the item. (Only one response per item)

_____ **1. DEPRESSED MOOD** (Sadness, hopeless, helpless, worthless)

0= Absent
1= These feeling states indicated only on questioning
2= These feeling states spontaneously reported verbally
3= Communicates feeling states non-verbally—i.e., through facial expression, posture, voice, and tendency to weep
4= Patient reports VIRTUALLY ONLY these feeling states in his spontaneous verbal and non-verbal communication

_____ **2. FEELINGS OF GUILT**

0= Absent
1= Self reproach, feels he has let people down
2= Ideas of guilt or rumination over past errors or sinful deeds
3= Present illness is a punishment. Delusions of guilt
4= Hears accusatory or denunciatory voices and/or experiences threatening visual hallucinations

_____ **3. SUICIDE**

0= Absent
1= Feels life is not worth living
2= Wishes he were dead or any thoughts of possible death to self
3= Suicidal ideas or gesture
4= Attempts at suicide (any serious attempt rates 4)

_____ **4. INSOMNIA EARLY**

0= No difficulty falling asleep
1= Complains of occasional difficulty falling asleep—i.e., more than 1/2 hour
2= Complains of nightly difficulty falling asleep

_____ **5. INSOMNIA MIDDLE**

0= No difficulty
1= Patient complains of being restless and disturbed during the night
2= Waking during the night—any getting out of bed rates 2 (except for purposes of voiding)

Adapted from Hedlung and Vieweg, The Hamilton rating scale for depression, *Journal of Operational Psychiatry*, 1979;10(2):149-165.

6. **INSOMNIA LATE**

_____ **0=** No difficulty
1= Waking in early hours of the morning but goes back to sleep
2= Unable to fall asleep again if he gets out of bed

7. **WORK AND ACTIVITIES**

_____ **0=** No difficulty
1= Thoughts and feelings of incapacity, fatigue or weakness related to activities; work or hobbies
2= Loss of interest in activity; hobbies or work—either directly reported by patient, or indirect in listlessness, indecision and vacillation (feels he has to push self to work or activities)
3= Decrease in actual time spent in activities or decrease in productivity
4= Stopped working because of present illness

8. **RETARDATION: PSYCHOMOTOR** (Slowness of thought and speech; impaired ability to concentrate; decreased motor activity)

_____ **0=** Normal speech and thought
1= Slight retardation at interview
2= Obvious retardation at interview
3= Interview difficult
4= Complete stupor

9. **AGITATION**

_____ **0=** None
1= Fidgetiness
2= Playing with hands, hair, etc.
3= Moving about, can't sit still
4= Hand wringing, nail biting, hair-pulling, biting of lips

10. **ANXIETY (PSYCHOLOGICAL)**

_____ **0=** No difficulty
1= Subjective tension and irritability
2= Worrying about minor matters
3= Apprehensive attitude apparent in face or speech
4= Fears expressed without questioning

11. **ANXIETY SOMATIC:** Physiological concomitants of anxiety, (i.e., effects of autonomic overactivity, "butterflies," indigestion, stomach cramps, belching, diarrhea, palpitations, hyperventilation, paresthesia, sweating, flushing, tremor, headache, urinary frequency). Avoid asking about possible medication side effects (i.e., dry mouth, constipation)

_____ **0=** Absent
1= Mild
2= Moderate
3= Severe
4= Incapacitating

12. SOMATIC SYMPTOMS (GASTROINTESTINAL)

_____ **0=** None
1= Loss of appetite but eating without encouragement from others. Food intake about normal
2= Difficulty eating without urging from others. Marked reduction of appetite and food intake

13. SOMATIC SYMPTOMS GENERAL

_____ **0=** None
1= Heaviness in limbs, back or head. Backaches, headache, muscle aches. Loss of energy and fatigability
2= Any clear-cut symptom rates 2

14. GENITAL SYMPTOMS (Symptoms such as: loss of libido; impaired sexual performance; menstrual disturbances)

_____ **0=** Absent
1= Mild
2= Severe

15. HYPOCHONDRIASIS

_____ **0=** Not present
1= Self-absorption (bodily)
2= Preoccupation with health
3= Frequent complaints, requests for help, etc.
4= Hypochondriacal delusions

16. LOSS OF WEIGHT

_____ **A.** When rating by history:
0= No weight loss
1= Probably weight loss associated with present illness
2= Definite (according to patient) weight loss
3= Not assessed

17. INSIGHT

_____ **0=** Acknowledges being depressed and ill
1= Acknowledges illness but attributes cause to bad food, climate, overwork, virus, need for rest, etc.
2= Denies being ill at all

18. DIURNAL VARIATION

_____ **A.** Note whether symptoms are worse in morning or evening. If NO diurnal variation, mark none
0= No variation
1= Worse in A.M.
2= Worse in P.M.

_____ **B.** When present, mark the severity of the variation. Mark "None" if NO variation
0= None
1= Mild
2= Severe

19. DEPERSONALIZATION AND DEREALIZATION (Such as: Feelings of unreality; Nihilistic ideas)

_____ **0**= Absent
1= Mild
2= Moderate
3= Severe
4= Incapacitating

20. PARANOID SYMPTOMS

_____ **0**= None
1= Suspicious
2= Ideas of reference
3= Delusions of reference and persecution

21. OBSESSIONAL AND COMPULSIVE SYMPTOMS

_____ **0**= Absent
1= Mild
2= Severe

Total Score _____

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Young Mania Rating Scale (YMRS)

Guide for Scoring Items – The purpose of each item is to rate the severity of that abnormality in the patient. When several keys are given for a particular grade of severity, the presence of only one is required to qualify for that rating.

The keys provided are guides. One can ignore the keys if that is necessary to indicate severity, although this should be the exception rather than the rule.

Scoring between the points given (whole or half points) is possible and encouraged after experience with the scale is acquired. This is particularly useful when severity of a particular item in a patient does not follow the progression indicated by the keys.

1. *Elevated Mood*
   - 0 Absent
   - 1 Mildly or possibly increased on questioning
   - 2 Definite subjective elevation; optimistic, self-confident; cheerful; appropriate to content
   - 3 Elevated, inappropriate to content; humorous
   - 4 Euphoric; inappropriate to content; singing

2. *Increased Motor Activity – Energy*
   - 0 Absent
   - 1 Subjectively increased
   - 2 Animated; gestures increased
   - 3 Excessive energy; hyperactive at times; restless (can be calmed)
   - 4 Motor excitement; continuous hyperactivity (cannot be calmed)

3. *Sexual Interest*
   - 0 Normal; not increased
   - 1 Mildly or possibly increased
   - 2 Definitive subjective increase on questioning
   - 3 Spontaneous sexual content; elaborates on sexual matters; hypersexual by self-report
   - 4 Overt sexual acts (towards patients, staff, or interviewer)

4. *Sleep*
   - 0 Reports no decrease in sleep
   - 1 Sleeping less than normal amount by up to one hour
   - 2 Sleeping less than normal by more than one hour
   - 3 Reports decreased need for sleep
   - 4 Denies need for sleep

5. *Irritability*
   - 0 Absent
   - 2 Subjectively increased
   - 4 Irritable at times during interview; recent episodes of anger or annoyance on ward
   - 6 Frequently irritable during interview; short, curt throughout
   - 8 Hostile, uncooperative; interview impossible

6. *Speech (Rate and Amount)*
   - 0 No increase
   - 2 Feels talkative
   - 4 Increased rate or amount at times, verbose at times
   - 6 Push; consistently increased rate and amount; difficult to interrupt
   - 8 Pressured; uninterruptible, continuous speech

7. *Language – Thought Disorder*
   - 0 Absent
   - 1 Circumstantial; mild distractibility; quick thoughts
   - 2 Distractible; loses goal of thought; changes topics frequently; racing thoughts
   - 3 Flight of ideas; tangentiality; difficult to follow; rhyming; echolalia
   - 4 Incoherent; communication impossible

8. *Content*
   - 0 Normal
   - 2 Questionable plans, new interests
   - 4 Special project(s); hyperreligious
   - 6 Grandiose or paranoid ideas; ideas of reference
   - 8 Delusions; hallucinations

9. *Disruptive – Aggressive Behavior*
   - 0 Absent; cooperative
   - 2 Sarcastic; loud at times; guarded
   - 4 Demanding; threats on ward
   - 6 Threatens interviewer; shouting; interview difficult
   - 8 Assaultive; destructive; interview impossible

10. *Appearance*
    - 0 Appropriate dress and grooming
    - 1 Minimally unkempt
    - 2 Poorly groomed; moderately disheveled; overdressed
    - 3 Disheveled; partly clothed; garish makeup
    - 4 Completely unkempt; decorated; bizarre garb

11. *Insight*
    - 0 Present; admits illness; agrees with need for treatment
    - 1 Possibly ill
    - 2 Admits behavior change, but denies illness
    - 3 Admits possible change in behavior, but denies illness
    - 4 Denies any behavior changes

Name: _____

Rater: _____

Date: _____

Score: _____

Name_____ Date_____

Sleep Quality Assessment (PSQI)

What is PSQI, and what is it measuring?

The Pittsburgh Sleep Quality Index (PSQI) is an effective instrument used to measure the quality and patterns of sleep in adults. It differentiates "poor" from "good" sleep quality by measuring seven areas (components): subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbances, use of sleeping medications, and daytime dysfunction over the last month.

INSTRUCTIONS:

The following questions relate to your usual sleep habits during the past month only. Your answers should indicate the most accurate reply for the majority of days and nights in the past month. Please answer all questions.

During the past month,

1. When have you usually gone to bed? _____
2. How long (in minutes) has it taken you to fall asleep each night? _____
3. What time have you usually gotten up in the morning? _____
4. A. How many hours of actual sleep did you get at night? _____
   B. How many hours were you in bed? _____

5. During the past month, how often have you had trouble sleeping because you	Not during the past month (0)	Less than once a week (1)	Once or twice a week (2)	Three or more times a week (3)
A. Cannot get to sleep within 30 minutes				
B. Wake up in the middle of the night or early morning				
C. Have to get up to use the bathroom				
D. Cannot breathe comfortably				
E. Cough or snore loudly				
F. Feel too cold				
G. Feel too hot				
H. Have bad dreams				
I. Have pain				
J. Other reason (s), please describe, including how often you have had trouble sleeping because of this reason (s):				
6. During the past month, how often have you taken medicine (prescribed or "over the counter") to help you sleep?				
7. During the past month, how often have you had trouble staying awake while driving, eating meals, or engaging in social activity?				
8. During the past month, how much of a problem has it been for you to keep up enthusiasm to get things done?				
9. During the past month, how would you rate your sleep quality overall?	Very good (0)	Fairly good (1)	Fairly bad (2)	Very bad (3)

Scoring

Component 1 #9 Score C1 _____

Component 2 #2 Score (<15min (0), 16-30min (1), 31-60 min (2), >60min (3))
+ #5a Score (if sum is equal 0=0; 1-2=1; 3-4=2; 5-6=3) C2 _____

Component 3 #4 Score (>7(0), 6-7 (1), 5-6 (2), <5 (3) C3 _____

Component 4 (total # of hours asleep) / (total # of hours in bed) x 100
>85%=0, 75%-84%=!, 65%-74%=2, <65%=3 C4 _____

Component 5 # sum of scores 5b to 5j (0=0; 1-9=1; 10-18=2; 19-27=3) C5 _____

Component 6 #6 Score C6 _____

Component 7 #7 Score + #8 score (0=0; 1-2=1; 3-4=2; 5-6=3) C7 _____

Add the seven component scores together _____ ***Global PSQI*** _____

A total score of "5" or greater is indicative of poor sleep quality.
If you scored "5" or more it is suggested that you discuss your sleep habits with a healthcare provider

The Epworth Sleepiness Scale

The Epworth Sleepiness Scale is widely used in the field of sleep medicine as a subjective measure of a patient's sleepiness. The test is a list of eight situations in which you rate your tendency to become sleepy on a scale of 0, no chance of dozing, to 3, high chance of dozing. When you finish the test, add up the values of your responses. Your total score is based on a scale of 0 to 24. The scale estimates whether you are experiencing excessive sleepiness that possibly requires medical attention.

How Sleepy Are You?

How likely are you to doze off or fall asleep in the following situations? You should rate your chances of dozing off, not just feeling tired. Even if you have not done some of these things recently try to determine how they would have affected you. For each situation, decide whether or not you would have:

- No chance of dozing =0
- Slight chance of dozing =1
- Moderate chance of dozing =2
- High chance of dozing =3

Write down the number corresponding to your choice in the right hand column. Total your score below.

Situation	Chance of Dozing
Sitting and reading	•
Watching TV	•
Sitting inactive in a public place (e.g., a theater or a meeting)	•
As a passenger in a car for an hour without a break	•
Lying down to rest in the afternoon when circumstances permit	•
Sitting and talking to someone	•
Sitting quietly after a lunch without alcohol	•
In a car, while stopped for a few minutes in traffic	•

Total Score = _____

Analyze Your Score

Interpretation:

0-7: It is unlikely that you are abnormally sleepy.
8-9: You have an average amount of daytime sleepiness.
10-15: You may be excessively sleepy depending on the situation. You may want to consider seeking medical attention.
16-24: You are excessively sleepy and should consider seeking medical attention.

Reference: Johns MW. A new method for measuring daytime sleepiness: The Epworth Sleepiness Scale. *Sleep* 1991; 14(6):540-5.

This printed version of the Epworth Sleepiness Scale is provided courtesy of Talk About Sleep, Inc. www.talkaboutsleep.com.

THE WORLD HEALTH ORGANIZATION QUALITY OF LIFE (WHOQOL) -BREF

The World Health Organization Quality of Life (WHOQOL)-BREF

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WHOQOL-BREF

The following questions ask how you feel about your quality of life, health, or other areas of your life. I will read out each question to you, along with the response options. **Please choose the answer that appears most appropriate.** If you are unsure about which response to give to a question, the first response you think of is often the best one.

Please keep in mind your standards, hopes, pleasures and concerns. We ask that you think about your life **in the last four weeks.**

		Very poor	Poor	Neither poor nor good	Good	Very good
1.	How would you rate your quality of life?	1	2	3	4	5

		Very dissatisfied	Dissatisfied	Neither satisfied nor dissatisfied	Satisfied	Very satisfied
2.	How satisfied are you with your health?	1	2	3	4	5

The following questions ask about **how much** you have experienced certain things in the last four weeks.

		Not at all	A little	A moderate amount	Very much	An extreme amount
3.	To what extent do you feel that physical pain prevents you from doing what you need to do?	5	4	3	2	1
4.	How much do you need any medical treatment to function in your daily life?	5	4	3	2	1
5.	How much do you enjoy life?	1	2	3	4	5
6.	To what extent do you feel your life to be meaningful?	1	2	3	4	5

		Not at all	A little	A moderate amount	Very much	Extremely
7.	How well are you able to concentrate?	1	2	3	4	5
8.	How safe do you feel in your daily life?	1	2	3	4	5
9.	How healthy is your physical environment?	1	2	3	4	5

The following questions ask about how completely you experience or were able to do certain things in the last four weeks.

		Not at all	A little	Moderately	Mostly	Completely
10.	Do you have enough energy for everyday life?	1	2	3	4	5
11.	Are you able to accept your bodily appearance?	1	2	3	4	5
12.	Have you enough money to meet your needs?	1	2	3	4	5
13.	How available to you is the information that you need in your day-to-day life?	1	2	3	4	5
14.	To what extent do you have the opportunity for leisure activities?	1	2	3	4	5

		Very poor	Poor	Neither poor nor good	Good	Very good
15.	How well are you able to get around?	1	2	3	4	5

		Very dissatisfied	Dissatisfied	Neither satisfied nor dissatisfied	Satisfied	Very satisfied
16.	How satisfied are you with your sleep?	1	2	3	4	5
17.	How satisfied are you with your ability to perform your daily living activities?	1	2	3	4	5
18.	How satisfied are you with your capacity for work?	1	2	3	4	5
19.	How satisfied are you with yourself?	1	2	3	4	5

20.	How satisfied are you with your personal relationships?	1	2	3	4	5
21.	How satisfied are you with your sex life?	1	2	3	4	5
22.	How satisfied are you with the support you get from your friends?	1	2	3	4	5
23.	How satisfied are you with the conditions of your living place?	1	2	3	4	5
24.	How satisfied are you with your access to health services?	1	2	3	4	5
25.	How satisfied are you with your transport?	1	2	3	4	5

The following question refers to how often you have felt or experienced certain things in the last four weeks.

		Never	Seldom	Quite often	Very often	Always
26.	How often do you have negative feelings such as blue mood, despair, anxiety, depression?	5	4	3	2	1

Do you have any comments about the assessment?

_____

_____

[The following table should be completed after the interview is finished]

		Equations for computing domain scores	Raw score	Transformed scores*	
				4-20	0-100
27.	**Domain 1**	(6-Q3) + (6-Q4) + Q10 + Q15 + Q16 + Q17 + Q18 ☐ + ☐ + ☐ + ☐ + ☐ + ☐ + ☐	a. =	b:	c:
28.	**Domain 2**	Q5 + Q6 + Q7 + Q11 + Q19 + (6-Q26) ☐ + ☐ + ☐ + ☐ + ☐ + ☐	a. =	b:	c:
29.	**Domain 3**	Q20 + Q21 + Q22 ☐ + ☐ + ☐	a. =	b:	c:
30.	**Domain 4**	Q8 + Q9 + Q12 + Q13 + Q14 + Q23 + Q24 + Q25 ☐ + ☐ + ☐ + ☐ + ☐ + ☐ + ☐ + ☐	a. =	b:	c:

* See Procedures Manual, pages 13-15

உலக சுகாதார நிறுவனம்

உங்களைப் பற்றிய சுய விவரம்

உங்களிடம் கேள்விகளை கேட்கும் முன்பாக உங்களைப் பற்றி அறிய விரும்புகின்றேன்.

சரியான பதிலை கொடுக்கப்பட்டுள்ள விடைகளில் இருந்து வட்டமிட்டு சுட்டி காட்டுக.

பாலினம் : ஆண் / பெண்

வயது :

கல்வி தகுதி : பள்ளிக்கு சென்றதில்லை / தொடக்கப் பள்ளி / நடுநிலைப் பள்ளி / மேல்நிலைப் பள்ளி

திருமணம் : ஆகவில்லை / ஆகிவிட்டது / சேர்ந்து வாழ்கின்றேன் / திருமணத்திற்குபின் பிரிந்து வாழ்கிறேன் / விவாகரத்தானவரா

கீழ்வரும் கேள்விகள் உங்களுடைய வாழ்க்கை தரக், நலம் போன்றவற்றை எவ்வாறு உணர்கின்றீர்க்ள் என்பதை பற்றியவையாகும். நான் கேள்விகளை ஒவ்வொன்றாக அதுனுடய சில பதில்களுடன் உங்களை கேட்கிறேன் அதற்கு நீங்கள் சரியான பதிலை தேர்ந்தெடுக்கவும். இதில் சரியான விடையை / பதிலை தேர்ந்தெடுக்க குழப்பழ்மென்றால் முதலில் சரி என்று உங்களுக்கு தோன்றியதே சரியாந விடையாகும்.

கடந்த 4 வாரங்களில் உங்களுடய வாழ்வின் மதிப்பு, எதிர்பார்ப்பு மற்றும் மனநிறைவு ஆகியவற்றை நினைவில் கொள்ளவும்.

		மிகவும் மோசம்	மோசம்	நன்றாக இல்லை மோசமாக இல்லை	நன்றாக உள்ளது	மிகவும் நன்றாக உள்ளது
1	உங்களுடைய வாழ்க்கையின் தரத்தை நிங்கள் எவ்வாறு மதிப்பிடுகிறீர்கள் ?	1	2	3	4	5

		மிகவும் மோசம்	மோசம்	நன்றாக இல்லை மோசமாக இல்லை	நன்றாக உள்ளது	மிகவும் நன்றாக உள்ளது
2	உங்களுடைய உடல் ஆரோக்கியம் எவ்வளவு திருப்திகரமாக உள்ளது?	1	2	3	4	5

கீழ்கண்ட வினாக்கள், நிங்கள் கடந்த 2 வாரங்களில், சில விஷயங்களில் அணுபவித்து வந்தீர்கள் (அணுபவம் உள்ளன) என்பதை பற்றி கேட்கின்றன.

		இல்லவே இல்லை	கொஞ் மளவு	மிதமான அளவு	அதிகமான அளவு	மிகவும் அதிகமான அளவு
3	எந்தளவிற்கு உடல் வலி நிங்கள் செய்ய வேண்டியவைகளிலி ருந்து உங்களை தடுக்கிறது ?	1	2	3	4	5
4	அன்றாட வாழ்வில் செயல்பட உங்களுக்கு எந்தளவிற்கு மருத்துவ உதவி தேயைவப்படுகிறது ?	1	2	3	4	5
5	வாழ்க்கையில் எந்தளவிற்கு சந்தோஷமாக உள்ளீர்கள் ?	1	2	3	4	5
6	உங்கள் வாழ்க்கை எந்தளவிற்கு அர்த்தமுள்ளதாக உணர்கிறீர்கள் ?	1	2	3	4	5
		இல்லவே இல்லை	கொஞ் மளவு	மிதமான அளவு	அதிகமான அளவு	மிகவும் அதிகமான அளவு
7	எந்தளவிற்கு நன்றாக உங்களால் கவனம் செலுத்த முடிகிறது?	1	2	3	4	5
8	உங்களுடைய அன்றாட வாழ்வில் எவ்வளவு பாதுகாப்பாக உணர்கிறீர்கள் ?	1	2	3	4	5
9	உங்கள் சுற்றுபுறம் எந்தளவு அரோக்கியமானதா க உள்ளது ?	1	2	3	4	5

கீழ்வரும் வினாக்கள், கடந்த இரண்டு வாரங்களில் நீங்கள் எவ்வளவு முழுமையாக அணுபவித்தீர்கள் அல்லது செய்ய முடிந்த சில காரியங்களை குறிப்பன.

		இல்லவே இல்லை	கொஞ் மளவு	மிதமான அளவு	அதிகமான அளவு	மிகவும் அதிகமான அளவு
10	தினசரி வாழ்க்கையில் உங்களுக்கு போதுமான அளவு சக்தி இருக்கிறதா ?	1	2	3	4	5
11	உங்கள் உடல் தோட்றத்தை உங்களால் ஏற்றுக் கொள்ள முடிகிறதா ?	1	2	3	4	5
12	உங்கள் தேவைகளை பூர்த்தி செய்ய உங்களிடத்தில் போதுமானளவு பணம் உள்ளதா ?	1	2	3	4	5
13	தினசரி வாழ்வில் உங்களுக்கு தேவையனா தகவல்கள் எவ்வளவு தூரம் கிடைக்கிறது ?	1	2	3	4	5
14	பொதுபோக்குகளில் ஈடுபட எந்த அளவிற்கு உங்களுக்கு வாய்ப்பு கிடைக்கிறது ?	1	2	3	4	5
15	எவ்வளவு நன்றாக உங்களால் அக்கம் பக்கத்தில் போய்வரமுடிகிறது ?	1	2	3	4	5

		இல்லவே இல்லை	கொஞ் மளவு	மிதமான அளவு	அதிகமான அளவு	மிகவும் அதிகமான அளவு
16	உங்கள் தூக்கம் எவ்வளவு திருப்திகரமாக உள்ளது ?	1	2	3	4	5
17	தினசரி செயல்களில் உங்களால் எவ்வளவு திருப்திகரமாக செயல்பட முடிகிறது ?	1	2	3	4	5
18	உங்கள் வேலைத்திறன் எவ்வளவு திருப்திகரமாக உள்ளது ?	1	2	3	4	5
19	உங்களைப்பற்றி நீங்கள் எவ்வளவு திருப்திகரமாக உள்ளீர்கள் ?	1	2	3	4	5

		இல்லவே இல்லை	கொஞ் மளவு	மிதமான அளவு	அதிகமான அளவு	மிகவும் அதிகமான அளவு
20	உங்கள் தனிப்பட்ட உறவுகள் குறித்து திருப்திகரமாக உள்ளீர்களா ?	1	2	3	4	5
21	உங்கள் தாம்பத்ய வாழ்க்கை எவ்வளவு திருப்திகரமாக உள்ளது ?	1	2	3	4	5
22	உங்கள் நண்பர்களிடம் இருந்து நீங்கள் பெறும் (உதவி) ஆதரவு எவ்வளவு திருப்திகரமாக உள்ளது ?	1	2	3	4	5
23	நீங்கள் வசிக்கும் இடத்தின் நிலை உங்களுக்கு எவ்வளவு திருப்திகரமாக உள்ளது ?	1	2	3	4	5
24	மருத்துவ வசதிகள் கிடைக்கபபெறுவதில் நிங்கள் திருப்திகரமாக உணர்கிறீர்களா ?	1	2	3	4	5
25	உங்கள் போக்குவரத்து வசதி எவ்வளவு திருப்திகரமாக உள்ளது ?	1	2	3	4	5

		இல்லவே இல்லை	கொஞ் மளவு	மிதமான அளவு	அதிகமான அளவு	மிகவும் அதிகமான அளவு
26	எவ்வளவு எளிதில் நீங்கள் சோகம், விரக்தி மற்றும் மன அழுத்தம் போன்ற எதிர்மறை எண்ணங்களுக்கு உளளாகிறீர்கள் ?	1	2	3	4	5
27	இந்தப் படிவத்தை பூர்த்தி செய்ய யாராவது தங்களுக்கு உதவி செய்தார்களா ?	1	2	3	4	5